

EPA Registration No.
36864-1
Vol. 1

Reg# 36864-1

Date of Application	Action code	Reference II	Event	Response Code
12/14/79	540	2	Shelf-life Stability data	35
1/12/80	345	271 ²⁷ 3	Increase Benzocaine to 1%	17
2/7/84	345	115265/3	Change in CSF	17
4/6/84	300	120857/4	Revised label	17
6/27/84	345	140455/5	Response to letter of 6/27/84	13
7/18/85	346	157321/5	Identification of Supplier	15
4/14/86	300	172394/6	Label update	17
12/3/87	300	232220		17
7/20/89	305	253,548/8		17
5/2/95	345	495242	New Basic	13
1/16/96	300	499175	Labeling	17
2/6/97	301			17



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JUN 26 2003

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Ms. Marcella L. Behan
Pierson Laboratories, Inc.
P.O. Box 157
Saluda, NC 28773

Subject: Revised Basic CSF
Chigg-Away
EPA Registration Number: 36864-1
Your Resubmission Dated June 11, 2003

Dear Ms. Behan:

The Confidential Statement of Formula (CSF), referred to above and submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable subject to the comments below. A copy of the CSF (Basic Formulation, dated June 11, 2002) has been placed in our file for the subject product. This CSF supersedes previously submitted CSFs for this product.

1. Please correct the following typographical errors on your file copies of the CSF. We have hand-corrected the Agency copy:
 - Correct the CAS No. for the ingredient, sulfur, to read: 7704-34-9.
 - Correct the % by weight of [REDACTED].
 - Include the total weight of [REDACTED] in block 17

If you have any questions regarding this action, please contact Susan Stanton of my team at (703) 305-5218.

Sincerely,

George T. LaRocca
Product Manager 13
Insecticide Branch
Registration Division (7505C)

Inert ingredient information may be entitled to confidential treatment
Manufacturing process information may be entitled to confidential treatment

Resubmission - SS
"response to 5/23/03 ltr"
cc: resubmission

G. LaRocca 740987
6-23-03

pierson laboratories, inc.

p.o. box 157
saluda, n.c. 28773

phone: (828) 749-9813
fax: (828) 749-9249

June 11, 2003

Mr. George T. LaRocca
Product Manager (13)
Insecticide Branch, Registration Division
Environmental Protection Agency
401 "M" Street, S.W.
Washington, DC 20460-0001

RE: Confidential Statement of Formula

Dear Mr. LaRocca:

In response to your letter of May 23, 2003, enclosed you will find the amended CSF for our product, Chigg-Away, 36864-1.

This should conclude the registration for this formula. I look forward to word of your acceptance.

Respectfully,

Marcella L. Behan

Marcella L. Behan
President

MLb
Enclosure





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MAY 23 2003

Ms. Marcella L. Behan
Pierson Laboratories, Inc.
P.O. Box 157
Saluda, NC 28773

Subject: Revised Basic CSF
Chigg-Away
EPA Registration Number: 36864-1
Your Resubmission Dated March 21, 2003

Dear Mr. McLane:

The Confidential Statement of Formula (CSF), dated 03/21/03, referred to above and submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, **will be acceptable** provided you make the following changes:

1. Include the CAS number of each ingredient under the ingredient name in column 10.
2. Include the full name of the ingredient [REDACTED] in column 10 and correct the certified limits of this ingredient (the decimal point is incorrectly placed).

Please submit a revised CSF incorporating the changes listed above. If you have any questions regarding this action, please contact Susan Stanton of my team at (703) 305-5218.

Sincerely,

A handwritten signature in cursive script that reads "Susan L. Stanton, for".

George T. LaRocca
Product Manager 13
Insecticide Branch
Registration Division (7505C)

DP BARCODE: D289440

CASE: 044141
SUBMISSION: S632825

DATA PACKAGE RECORD
BEAN SHEET

DATE: 04/10/03
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 346 .. RESUBMISSION
RANKING : 5 POINTS ()
CHEMICALS: 077501 Sulfur 10.0000%
097001 Benzocaine 03.0000%

ID#: 036864-00001 CHIGG AWAY
COMPANY: 036864 PIERSON LABORATORIES INC.
PRODUCT MANAGER: 03 ARNOLD LAYNE 703-305-6249 ROOM: CM2 212
PM TEAM REVIEWER: SUSAN STANTON 703-305-5218 ROOM: CM2 237
RECEIVED DATE: 04/04/03 DUE OUT DATE: 07/03/03

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 289440 EXPEDITE: N DATE SENT: 04/10/03 DATE RET.: / /
CHEMICAL: 077501 Sulfur
DP TYPE: 001 Submission Related Data Package
CSF: Y LABEL: Y

ASSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: 6-2-03
DIV : RD / / / /
BRAN: TRB / / / /
SECT: CHEM / / / /
REVR : / / / /
CONTR: / / / /

* * * DATA REVIEW INSTRUCTIONS * * *

Please review the revised basic CSF for this product and determine whether it is acceptable. Copies of the 2 most recently accepted CSFs and the latest label are included for your information.

Thanks,
Susan Stanton

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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DATE OUT: 14 May 2003

SUBJECT: EP [x] MP [] PRODUCT CHEMISTRY REVIEW

DP BARCODE No.: D289440

REG./File Symbol No.: 36864-1

PRODUCT NAME: Chigg Away

COMPANY: Pierson Laboratories Inc.

FOOD USE: [] PC CODE: 77501 & 97001

TO: PM #03, Cynthia Giles-Parker/Susan Stanton
Insecticide Branch
Registration Division (7505C)

FROM: Bruce F. Kitchens, Chemist
Technical Review Branch
Registration Division (7505C)

SRW 5/14/03
Bruce F. Kitchens
5/14/03

INTRODUCTION:

This submission is a resubmission. The registrant, Pierson Laboratories Incorporated, is responding to a previous Agency review. In that review it was determined that a revised basic Confidential Statement of Formula (CSF) would have to be submitted to the Agency to correct errors on the CSF. The active ingredients in this product are Sulfur and Benzocaine at label nominal concentrations of 10% and 3.0%, respectively. This product is intended for use as an insect repellent. In support of this response, the registrant has submitted a revised basic CSF dated 21 Mar 2003. The Technical Review Branch (TRB) has been asked to review this submission.

SUMMARY OF FINDINGS:

TRB has reviewed this submission and reports the following findings:

1. This product is produced from a registered source of the active ingredient.
2. All inert ingredients are cleared for use in formulated products.
3. The nominal concentration of the active ingredient listed on the revised basic CSF the draft label are the same.

4. The active ingredients certified limits as proposed on the revised CSF are acceptable. However, one inert ingredient lists incorrect certified limits. See confidential appendix for details.

CONCLUSIONS:

TRB has reviewed this submission and concludes the following:

1. The revised basic formula CSF for the registered end-use product, Chigg Away dated 21 Mar 2003 is not acceptable. The upper and lower certified limits appear to have incorrect placement of the decimal point. Inform the registrant that a revised CSF should be submitted to the Agency which this deficiency. Also, inform the registrant that CAS Reg. No. should be listed on the CSF under the name of each ingredient.

CONFIDENTIAL APPENDIX

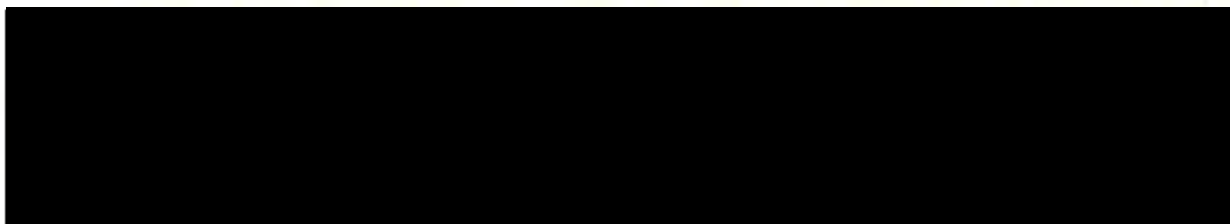
EP [x] MP [] PRODUCT CHEMISTRY REVIEW

BARCODE No.: D289440 REG./File Symbol No.: 36864-1

PRODUCT NAME: Chigg Away

Reviewer: BKitchens Company: Pierson Laboratories, Inc.

1.



346-55

B. LaRocca
4-2-03

pierson laboratories, inc.

p.o. box 157
saluda, n.c. 28773

phone: (828) 749-9813
fax: (828) 749-9249

March 21, 2003

Mr. George T. LaRocca
Product Manager (13)
Insecticide Branch, Registration Division
Environmental Protection Agency
401 "M" Street S.W.
Washington, DC 20460-0001

Re: Confidential Statement of Formula

Dear Mr. LaRocca:

Enclosed please find the corrections to EPA Form 85770-4, Confidential Statement of Formula, per your letter of March 3, 2003. We are now using Cosmetic Concepts, Inc. in Swannanoa, NC as our producer. Their EPA Est. Number is 068807-NC-001.

I look forward to hearing from you regarding the approval of this form. Your attention to this matter is very much appreciated.

Respectfully,

Marcella L. Behan

Marcella L. Behan
President

mlb
Enclosure



not possible. Must have been 4/4/03.

346-55

4-2-03



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MAR 3 2003

Marcella L. Behan, President
Pierson Laboratories, Inc.
P.O. Box 157
Saluda, N.C. 28773

Subject: Revised Basic Confidential Statement of Formula
Chigg-Away
EPA Registration Number: 36864-1
Your Submission Dated February 18, 2003

Dear Ms. Behan:

The revised Confidential Statement of Formula (CSF), referred to above and submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is not acceptable for the following reasons:

1. The CSF is not filled out completely. You must complete blocks B (# of pages), 5 (PM 13, George LaRocca), 16, 18, 19, 20, and 21.
2. In column 11, you must include the supplier's name and address, as on the previously approved CSF, dated 2/10/01.
3. You must include upper and lower certified limits in column 14 as on the previously approved CSF, dated 2/10/01.
4. The active ingredient, sulfur, should be listed first as on the previously approved CSF, dated 2/10/01.
5. You must correct the registration number given in block 4.
6. Each ingredient in the formulation should be listed on a separate line of the CSF to avoid confusion.

-2-

If you have any questions regarding this action, please contact Susan Stanton of my team at (703) 305-5218.

Sincerely,

A handwritten signature in cursive script that reads "Susan L. Stanton, for".

George T. LaRocca
Product Manager 13
Insecticide Branch
Registration Division (7505C)

345-55-Chem

George LaRocca
2-27-03

pierson laboratories, inc.

p.o. box 157
saluda, n.c. 28773

phone: (828) 749-9813
fax: (828) 749-9249

February 18, 2003

Mr. George T. LaRocca
Product Manager (13)
Insecticide Branch, Registration Division
Environmental Protection Agency
401 "M" Street S.W.
Washington, DC 20460-0001

Re: Confidential Statement of Formula

Dear Mr. LaRocca:

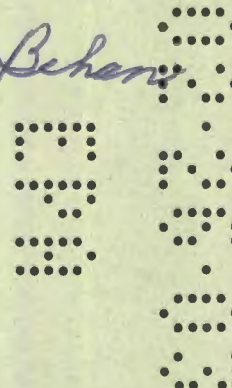
Enclosed please find EPA Form 85770-4, Confidential Statement of Formula. We are now using Cosmetic Concepts, Inc. in Swannanoa, NC as our producer. Their EPA Est. Number is 068807-NC-001.

I look forward to hearing from you regarding the approval of this form. Your attention to this matter is very much appreciated.

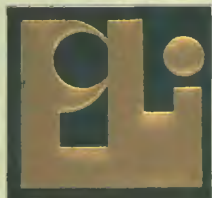
Respectfully,

Marcella L. Behan

Marcella L. Behan
President



mlb
Enclosure





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MAR 5 2001

Marcella Behan, President
Pierson Laboratories, Inc.
P.O. Box 157
Saluda, NC 28773

Subject: Amendment: Updated Confidential Statement of Formula (CSF)
Chigg-Away
EPA Registration No. 36864-1
Your submission dated February 20, 2001

Dear Ms. Behan:

The revised basic Confidential Statement of Formula (CSF), dated February 10, 2001, has been reviewed by the Agency and is acceptable. A copy of the CSF has been placed in the product file for the subject product. A stamped copy of the label is enclosed for your records.

If you have any questions regarding this action, please contact Dr. William Sproat of my team at (703) 308-8587.

Sincerely,

A handwritten signature in black ink, appearing to read "George T. LaRocca".

George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division (7505C)

Enclosure

7505C
SPROAT
03/05/01



pierson laboratories, inc.

p.o. box 157 saluda, n.c. 28773 828/749-9813

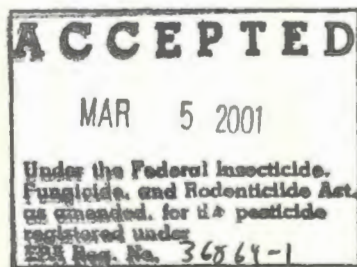
fax:828/749-9249

e-mail: piersonlabs@a-o.com

www.chiggaway.com

PRODUCT NAME: Chigg-Away

EPA# 36864-1



1. **RELIEVES ITCHING** due to insect bites, such as chiggers (redbugs), mosquitoes, ticks, fleas, fire ants; minor stings.

2. **REPELS CHIGGERS** (redbugs)

ACTIVE INGREDIENTS: Precipitated sulfur U.S.P. 10.0%

*INERT INGREDIENTS: 90.0%

*Contains 3% Active Benzocaine

KEEP OUT OF THE REACH OF CHILDREN
CAUTION: SEE BACK PANEL FOR
ADDITIONAL PRECAUTIONS

NET 4 FL. OZ. (118ML)

NDC 45991-003-04

8840-01-137-8468

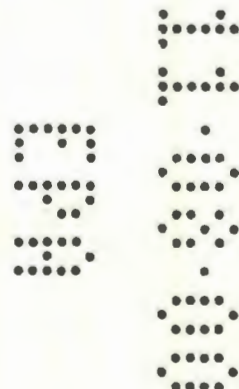
THE SOLDIER'S CHOICE

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

INDICATION: **RELIEVES ITCHING** and discomfort due to nonpoisonous insect bites such as chiggers (redbugs), mosquitoes, ticks, sand fleas, no-see-ums, biting flies, fire ants, bees and wasps; swimmers itch. DIRECTIONS: Apply topically and rub in well as needed. The unique action of CHIGG-AWAY lotion carries prompt relief to the source of irritation. Provides soothing relief from itching. **WARNINGS** (Red Box): **CAUTION**. DIRECTIONS: Apply around feet, ankles, waist and to skin under all areas of tight clothing and around all openings in outer clothing. Reapply after heavy perspiration. PRECAUTIONARY STATEMENTS: Hazards to Humans Caution: For external use only. Keep away from eyes or other mucous membranes. Not for prolonged use. If the condition for which this product is used persists or if a rash or irritation develops, discontinue use and consult a physician. For use on intact skin only. Do not use on children younger than two years. As with all pesticides/drugs, keep out of the reach of children. In case of accidental ingestion, contact a physician or poison control center at once. DISPOSAL: Do not reuse bottle. Rinse thoroughly before discarding.

NDC NO: 45991-002-04
EPA REG. NO: 36864-1
EPA EST. NO: 72917-NC-001

Manufactured for:
PIERSON LABORATORIES, INC.
P.O. BOX 157, SALUDA, NC 28773
www.chiggaway.com



Submission - WS - Chem
(15 pages)

George
LaRocca
2/26/01

pierson laboratories, inc.

p.o. box 157
saluda, n.c. 28773

phone: (828) 749-9813
fax: (828) 749-9249

February 20, 2001

Mr. George T. LaRocca
Product Manager (13)
Insecticide Branch, Registration Division
Environmental Protection Agency
401 "M" Street S.W.
Washington, DC 20460-0001

RE: Updated Confidential Statement of Formula
Chigg-Away
EPA Reg. No. 36864-1

Dear Mr. LaRocca:

Enclosed please find the updated Confidential Statement of Formula.

You currently have our label that was submitted November 2, 2000 upon which we are awaiting approval.

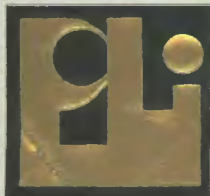
Hopefully we can get these two documents approved and move on with business. I appreciate your help in getting all this correct and approved.

Respectfully,

Marcella L. Behan

Marcella L. Behan
President

mlb
Enclosures





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 18 2001

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Marcella Behan
President
Pierson Laboratories, Inc.
P.O. Box 157
Saluda, NC 28773

Subject: Updated Confidential Statement of Formula
Chigg-Away
EPA Reg. No. 36864-1
Your submission dated November 2, 2000

Dear Ms. Behan:

The Agency has reviewed your application for an updated confidential statement of formula (CSF) for EPA Registration No. 36864-1. The CSF, dated November 2, 2000 is unacceptable for the reasons listed below.

1. There is no total weight given in block 17 of the CSF.
2. The upper and lower certified limits for the active ingredient and all the inert ingredients have been calculated incorrectly. The submitted CSF is not in compliance with PR Notice 91-2, which requires the upper and lower certified limits to be calculated based on the nominal concentration, according to the table listed in 40 CFR 158.175(b)(2). Refer to the enclosure for correct values and certified limits and then resubmit the CSF.

The label will be reviewed upon submission of a correct CSF. If you have any questions, please call Dr. William Sproat of my team at 703-308-8587.

Sincerely,

George T. LaRocca
Product Manager 13
Insecticide Branch
Registration Division (7505C)

Enclosure

7505C
SPROAT
01/18/01

#11239

DP BARCODE: D270617

CASE: 044141
SUBMISSION: S588378

DATA PACKAGE RECORD
BEAN SHEET

DATE: 11/21/00
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 345 TECH-FORMULA CHANGE AMND
RANKING : 5 POINTS ()
CHEMICALS: 077501 Sulfur 10.0000%
097001 Benzocaine 03.0000%

ID#: 036864-00001 CHIGG AWAY
COMPANY: 036864 PIERSON LABORATORIES INC.
PRODUCT MANAGER: 03 ARNOLD LAYNE 703-305-6249 ROOM: CM2 212
PM TEAM REVIEWER: WILLIAM SPROAT 703-308-8587 ROOM: CM2 208
RECEIVED DATE: 11/08/00 DUE OUT DATE: 02/06/01

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 270617 EXPEDITE: N DATE SENT: 11/21/00 DATE RET.: / /
CHEMICAL: 077501 Sulfur
DP TYPE: 001 Submission Related Data Package
CSF: Y LABEL: Y
ASSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: ~~01/05/01~~ 1-11-01
DIV : RD / / / / NEGOT DATE: / /
BRAN: TRB / / / / PROJ DATE: / /
SECT: CHEM / / / /
REVR : *S.B. mather* 12/27/00 01/02/00
CONTR: / / / /

* * * DATA REVIEW INSTRUCTIONS * * *

Please review the enclosed label, existing CSF dated 11/5/84, and proposed alternate CSF dated 11/02/2000 for EPA Reg. No. 36864-1.

Thanks

Bill Sproat
308-8587

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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DATE: 02/JAN/2001

SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]
DP BARCODE No.: D270617 REG./File Symbol No.: 36864-1
PRODUCT NAME: Chigg Away
COMPANY: Pierson Laboratories Incorporation

FROM: Shyam B. Mathur, Chemist
Product Chemistry Team
Technical Review Branch/RD (7505C)

S. Mathur
01/02/01

TO: Arnold Layne, PM 03
Insecticide Branch/RD(7505C)

INTRODUCTION

The registrant has submitted a CSF for alternate formulation to support the registration of the end-use product Chigg Away.

SUMMARY OF FINDINGS

1. The subject product contains Sulfur [REDACTED] as the active ingredient with product label claim of 10.0%.
2. All the inert ingredients used in the formulation are cleared by the Agency.
3. The upper and lower certified limits for all the inert ingredients have been calculated incorrectly.

CONCLUSION:

The TRB has reviewed the CSF for alternate formulation (dated 11-02-00) submitted for the end-use product Chigg Away and has determined that it is not acceptable for the following reasons:

1. There is no total weight given in the Block # 17.
2. The CSF submitted is not in compliance with PR Notice 91-2. According to which the upper and lower certified limits must be calculated based on the nominal concentration following the table given in 40CFR §158.175b2. The upper and lower certified limits for the active ingredient and all the inert ingredients have been calculated incorrectly. The correct values have been shown in Confidential Appendix.

The registrant must correct all the errors and resubmit the CSF.

Inert ingredient information may be entitled to confidential treatment

CONFIDENTIAL APPENDIX

SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]
DP BARCODE No.: D270617 REG./File Symbol No.: 36864-1
PRODUCT NAME: Chigg Away
COMPANY: Pierson Laboratories Incorporation

Ingredient (s)	% by weight		
	NC	UCL	LCL



100.00%

The Upper and lower certified limits are calculated by using the standard table given 40CFR§158.175 (b) (2).

345-WS-Chem

George
LaRocca
11/9/00

pierson laboratories, inc.

p.o. box 157
saluda, n.c. 28773

phone: (828) 749-9813
fax: (828) 749-9249

e-mail: piersonlabs@a-o.com
www.chiggaway.com

November 2, 2000

Mr. George T. LaRocca
Product Manager (13)
Insecticide Branch, Registration Division
Environmental Protection Agency
401 "M" Street S.W.
Washington, DC 20460-0001

RE: Updated Labels and Confidential Statement of Formula
EPA Registration Number 36864-1

Dear Mr. LaRocca:

Enclosed you will find two copies of our new product label. If this label meets with your approval, please send a stamped copy of approval for our records.

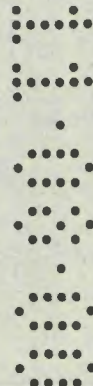
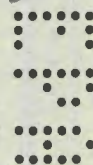
Also enclosed is a new copy of our Confidential Statement of Formula. The only change is the one you recommended in your letter of July 7, 2000. We are now obtaining our sulfur from [REDACTED] Our new producer is The Grayson O. Group and their EPA Establishment Number is 72917NC-001.

I look forward to hearing from you with approval on each of these documents. Thank you for your help in this matter.

Sincerely,

Marcella L. Behan

Marcella L. Behan
President



mlb
Enclosures





ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS (TS - 767)
WASHINGTON, DC 20460

NOTICE OF SUPPLEMENTAL REGISTRATION OF DISTRIBUTOR

(Please read instructions before completing)

INSTRUCTIONS

After a registrant has obtained final registration for the basic product, the registrant may then supplementally register and distribute his/her product. One form must be submitted for each distributor brand and must be signed by the distributor involved. The form must state the basic registration number and the distributor company number.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationary, to the Registration Division to have a number assigned prior to submitting a Distributor Notification to the Agency.

Notification forms must be submitted by the basic registrant. They must have the concurrence and signature of both the registrant and the distributor.

When submitting several forms for the same basic product, submitting them together will facilitate processing.

NOTE: DO NOT submit distributor product labels.

CONDITIONS

1. The distributor product must have the same composition as the basic registered product.
2. The distributor brand product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so no other changes are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic registered product, followed by a hyphen and the distributor's company number.
6. Distributor products must bear the name and address of the distributor qualified by such terms as "packed for . . ." "distributed by . . ."; or "sold by . . ." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor brand products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

RECEIVED BY EPA REGISTRATION
DIVISION ON THE DATE STAMPED
BELOW



1-15-88

EPA REGISTRATION NO. OF PRODUCT	DISTRIBUTOR COMPANY NUMBER
36864-1 4-b-1-2	49801

NAME AND ADDRESS OF BASIC REGISTRANT (print or type; include ZIP code)

Pierson Laboratories, Inc.
171 Lake Hosea Rd., P.O. Box 157
Saluda, NC 28773

NAME OF REGISTERED PRODUCT (basic product name accepted by EPA)

Chigg Away

DISTRIBUTOR PRODUCT NAME

Chigg Away

NAME AND ADDRESS OF DISTRIBUTOR (print or type; include ZIP code)

Bioline Laboratories
1900 W. Commercial Blvd.
Ft. Lauderdale, FL 33309

DISTRIBUTOR

We intend to market under the Distributor Product Name and Number specified above, subject to the conditions specified on this form.

SIGNATURE AND TITLE OF DISTRIBUTOR	DATE
<i>[Signature]</i> Dir.-Regulatory Affairs	1/5/88

REGISTRANT

It is requested that the Registration Record of this jacket include the Distributor Product specified above, subject to the conditions specified on this form.

SIGNATURE AND TITLE OF REGISTRANT	DATE
<i>Marcella L. Behan, President</i>	1/11/88



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JUL 7 2000

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Marcella L. Behan
President
Pierson Laboratories, Inc.
Post Office Box 157
Saluda, North Carolina 28773

Dear Ms. Behan:

SUBJECT: Amendment - Updated Labels and Source of Sulfur Product Name
EPA Registration Number 36864-1
Your Application Dated June 20, 2000

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is not acceptable for the following reasons:

The source product for precipitated sulfur, USP is not registered and thus unacceptable. You must specify a currently registered source product under column 12 of the confidential statement of formula. We had brought this to your attention in our letter of January 24, 1996 (copy enclosed). In your July 18, 1985 letter you indicated [REDACTED], as your source of active ingredient. This source of registered technical sulfur would be acceptable.

If you have any questions in regard to this letter please contact me at 703/305-6100.

Sincerely yours,

George T. LaRocca
Product Manager 13
Pesticide Branch
Registration Division 7505C

Enclosure

pierson laboratories, inc.

p.o. box 157
saluda, n.c. 28773

phone: (828) 749-9813
fax: (828) 749-9249

June 20, 2000

Mr. George T. LaRocca
Product Manager (13)
Insecticide Branch, Registration Division
Environmental Protection Agency
401 "M" Street S.W.
Washington, DC 20460-0001

Re: Updated Labels and Confidential Statement of Formula
EPA Registration Number 36864-1
Your letter dated September 30, 1999


Dear Mr. LaRocca:

Enclosed is two copies of our new product label. As requested in your last letter, an asterisk has been added before Inert Ingredients. If this label meets with your approval, please send a stamped copy of approval for our records.

Also enclosed is a new copy of our Confidential Statement of Formula. The formula is the same as the one of record dated November 5, 1984. The only change is the name of the Producer. Our new formulator is The Grayson O. Group and their EPA Establishment Number is 72917-N C-001.

Hopefully this puts all our records in order. I look forward to hearing from you regarding the approval of each document.

Respectfully,

Marcella L. Behan 

Marcella L. Behan
President

mlb
Enclosures





pierson laboratories, inc.

p.o. box 157 saluda, n.c. 28773 828/749-9813

fax: 828/749-9249

e-mail: piersonlabs@a-o.com

www.chiggaway.com

PRODUCT NAME: Chigg-Away

EPA REG. NO: 36864-1



1. **RELIEVES ITCHING** due to insect bites, such as chiggers (redbugs), mosquitoes, ticks, fleas, fire ants; minor stings.

2. **REPELS CHIGGERS** (redbugs)

ACTIVE INGREDIENTS: Precipitated sulfur U.S.P. 10.0%

*INERT INGREDIENTS: 90.0%

*Contains 3% Active Benzocaine

KEEP OUT OF THE REACH OF CHILDREN

CAUTION: SEE BACK PANEL FOR ADDITIONAL PRECAUTIONS

NET 4 FL. OZ. (118ML)

NDC 46891-002-04

8848-01-137-9485

"THE SOLDIER'S CHOICE"

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

INDICATION: **RELIEVES ITCHING** and discomfort due to nonpoisonous insect bites such as chiggers (redbugs), mosquitoes, ticks, and fleas, no-see-ums, biting flies, fire ants, bees and wasps; swimmers itch. DIRECTIONS: Apply topically and rub in well as needed. The unique action of CHIGG-AWAY lotion carries prompt relief to the source of irritation. Provides soothing relief from itching.

REPELS CHIGGERS (redbugs). DIRECTIONS: Apply around feet, ankles, waist and to skin under all areas of tight clothing and around all openings in outer clothing. Reapply after heavy perspiration.

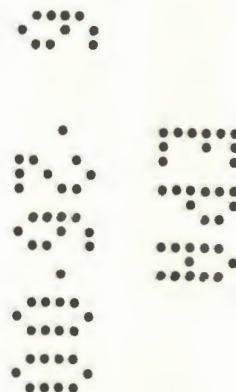
PRECAUTIONARY STATEMENTS: Hazards to Humans Caution: For external use only. Keep away from eyes or other mucous membranes. Not for prolonged use. If the condition for which this product is used persists or if a rash or irritation develops, discontinue use and consult a physician. For use on intact skin only. Do not use on children younger than two years. As with all pesticides/drugs, keep out of the reach of children. In case of accidental ingestion, contact a physician or poison control center at once. **DISPOSAL:** Do not reuse bottle. Rinse thoroughly before discarding.

NDC NO: 46891-002-04

EPA REG. NO: 36864-1

EPA EST. NO: 72917-NC-001

Manufactured for:
PIERSON LABORATORIES, INC.
P.O. BOX 157, SALUDA, NC 28773
www.chiggaway.com





pierson laboratories, inc.

p.o. box 157 saluda, n.c. 28773 828/749-9813

fax: 828/749-9249

e-mail: piersonlabs@a-o.com

www.chiggaway.com

PRODUCT NAME: Chigg-Away

EPA REG. NO: 36864-1



1. **RELIEVES ITCHING** due to insect bites, such as chiggers (redbugs), mosquitoes, ticks, fleas, fire ants; minor stings.
2. **REPELS CHIGGERS** (redbugs)

ACTIVE INGREDIENTS: Precipitated sulfur U.S.P. 10.0%

*INERT INGREDIENTS: 90.0%

*Contains 3% Active Benzocaine

KEEP OUT OF THE REACH OF CHILDREN
CAUTION: SEE BACK PANEL FOR
ADDITIONAL PRECAUTIONS

NET 4 FL. OZ. (118ML)

NDC 45891-008-04

8048-01-137-0485

THE SOLDIER'S CHOICE[®]

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

INDICATION: **RELIEVES ITCHING** and discomfort due to nonpoisonous insect bites such as chiggers (redbugs), mosquitoes, ticks, sand flies, no-see-ums, biting flies, fire ants, bees and wasps; swimmers itch. DIRECTIONS: Apply topically and rub in well as needed. The unique action of Chigg-Away lotion carries prompt relief to the source of irritation. Provides soothing relief from itching.

REPELS CHIGGERS (redbugs). DIRECTIONS: Apply around feet, ankles, waist and to skin under all areas of tight clothing and around all openings in outer clothing. Reapply after heavy perspiration.

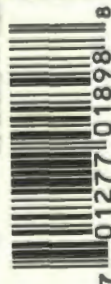
PRECAUTIONARY STATEMENTS: Hazards to Humans Caution: For external use only. Keep away from eyes or other mucous membranes. Not for prolonged use. If the condition for which this product is used persists or if a rash or irritation develops, discontinue use and consult a physician. For use on infant skin only. Do not use on children younger than two years. As with all pesticide/drugs, keep out of the reach of children. In case of accidental ingestion, contact a physician or poison control center at once. DISPOSAL: Do not reuse bottle. Rinse thoroughly before discarding.

NDC NO: 45891-002-04

EPA REG. NO: 36864-1

EPA EST. NO: 72917-NC-001

Manufactured for:
PIERSON LABORATORIES, INC.
P.O. BOX 157, SALUDA, NC 28773
www.chiggaway.com



300 ~~5569171~~
17/17

SEP 30 1999

Marcella I. Behan
President
Pierson Laboratories, Inc.
Post Office Box 157
Saluda, North Carolina 28773

Dear Ms. Behan:

SUBJECT: Updated Labels
Chigg Away
EPA Registration Number 36864-1
Your Letter Dated June 25, 1999

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable subject to the comments listed below. Two copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy is enclosed for your records.

1. Refer to comment 1 of our June 10, 1997 letter and add an asterisk to Inert Ingredients.

With respect to your request for formula changes we assume you are referring to your request dated May 2, 1995. We do not have a submission dated May 1996. We note your request to withdraw this change. Thus the Confidential Statement of Formula (CSF) dated May 2, 1995 is void. The CSF of record is dated November 5, 1984. If this is incorrect please let me know.

If you have any questions please do not hesitate to call me at 703/305-6100.

Sincerely yours,

George T. LaRocca
Product Manager (13)
Insecticide Branch
Registration Division

Return letter

*George LaRocca
7/7/99*

pierson laboratories, inc.

p.o. box 157
saluda, n.c. 28773

phone: (828) 749-9813
fax: (828) 749-9249

June 25, 1999

Mr. George LaRocca, Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (7505C)
Environmental Protection Agency
401 "M" Street S.W.
Washington, DC 20460-0001

Dear Mr. LaRocca:

As requested, enclosed you will find two copies of our new label for our product Chigg-Away. It took awhile to use up all the old label, but here is the new one with all the changes requested.

We wish to cancel our request of May, 1996 for changes in our inert ingredients. Our formulator at that time had made the suggestion to us for changes, but we since have had second thoughts. We wish to keep our original formulation that you have on file.

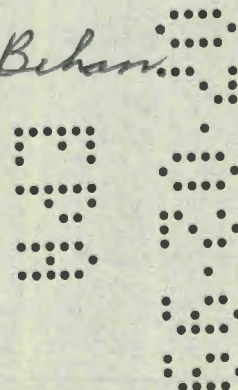
I look forward to receiving a stamped approval of this label from you.

Respectfully,

Marcella L. Behan

Marcella L. Behan
President

mlb
Enclosures



pierson laboratories, inc.

p.o. box 157
saluda, n.c. 28773

phone: (828) 749-9813
fax: (828) 749-9249

PRODUCT NAME: CHIGG-AWAY
EPA REG. NUMBER: 36864-1

**CHIGG
AWAY**

TWO WAY ACTION

1-RELIEVES ITCHING DUE TO INSECT BITES SUCH AS CHIGGERS (REDBUGS), MOSQUITOES, TICKS, FLEAS, FIRE ANTS; MINOR STINGS.

2-REPELS CHIGGERS (REDBUGS)

ACTIVE INGREDIENTS: Precipitated Sulfur U.S.P. 10.0%
INERT INGREDIENTS: 90%
*Contains 3% Active Benzocaine for Itch Relief

KEEP OUT OF THE REACH OF CHILDREN.
CAUTION: SEE BACK PANEL FOR ADDITIONAL PRECAUTIONS

NET 4 FL. OZ. (118ML)

NDC 45591-002-04

6840-01-137-8456

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

INDICATION: RELIEVES ITCHING and discomfort due to nonpoisonous insect bites such as chiggers (redbugs), mosquitoes, ticks, sand fleas, no-see-ums, biting flies, fire ants, bees and wasps; swimmers itch. **DIRECTIONS:** Apply topically and rub in well as needed. The unique action of CHIGG-AWAY lotion carries prompt relief to the source of irritation. Provides soothing relief from itching.

REPELS CHIGGERS (REDBUGS). **DIRECTIONS:** Apply around feet, ankles, waist and to skin under all areas of tight clothing and around all openings in outer clothing. Reapply after heavy perspiration.

PRECAUTIONARY STATEMENTS: Hazards to Humans Caution: For external use only. Keep away from eyes or other mucous membranes. Not for prolonged use. If the condition for which this product is used persists or if a rash or irritation develops, discontinue use and consult a physician. For use on intact skin only. Do not use on children younger than two years. As with all pesticides/drugs, keep out of the reach of children. In case of accidental ingestion, contact a physician or poison control center at once.

DISPOSAL: Do not reuse bottle. Rinse thoroughly before discarding.

NDC NO: 45591-002-04
EPA REG. NO: 36864-1
EPA EST-3300-KS-001

Manufactured for:
PIERSON LABORATORIES, INC.
P.O. BOX 157, SALUDA, NC 28773

7 01277 01898 8

ACCEPTED
with COMMENTS
in EPA Letter Dated

SEP 30 1999

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

36864-1



pierson laboratories, inc.

p.o. box 157
saluda, n.c. 28773

phone: (828) 749-9813
fax: (828) 749-9249

PRODUCT NAME: CHIGG-AWAY
EPA REG. NUMBER: 36864-1



TWO WAY ACTION

1-RELIEVES ITCHING DUE TO INSECT BITES SUCH AS CHIGGERS (REDBUGS), MOSQUITOES, TICKS, FLEAS, FIRE ANTS; MINOR STINGS.

2-REPELS CHIGGERS (REDBUGS)

ACTIVE INGREDIENTS: Precipitated Sulfur U.S.P. 10.0%,
INERT INGREDIENTS: 90%

*Contains 3% Active Benzocaine for Itch Relief

KEEP OUT OF THE REACH OF CHILDREN.
CAUTION: SEE BACK PANEL FOR
ADDITIONAL PRECAUTIONS

NET 4 FL. OZ. (118ML)

NDC 45591-002-04

6840-01-137-8456

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

INDICATION: RELIEVES ITCHING and discomfort due to nonpoisonous insect bites such as chiggers (redbugs), mosquitoes, ticks, sand fleas, no-see-ums, biting flies, fire ants, bees and wasps; swimmers itch. **DIRECTIONS:** Apply topically and rub in well as needed. The unique action of CHIGG-AWAY lotion carries prompt relief to the source of irritation. Provides soothing relief from itching.

REPELS CHIGGERS (REDBUGS). **DIRECTIONS:** Apply around feet, ankles, waist and to skin under all areas of tight clothing and around all openings in outer clothing. Reapply after heavy perspiration.

PRECAUTIONARY STATEMENTS: Hazards to Humans Caution:

For external use only. Keep away from eyes or other mucous membranes. Not for prolonged use. If the condition for which this product is used persists or if a rash or irritation develops, discontinue use and consult a physician. For use on intact skin only. Do not use on children younger than two years. As with all pesticides/drugs, keep out of the reach of children. In case of accidental ingestion, contact a physician or poison control center at once.

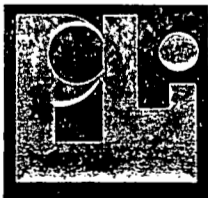
DISPOSAL: Do not reuse bottle. Rinse thoroughly before discarding.

NDC NO: 45591-002-04

EPA REG. NO: 36864-1

EPA EST-9300-KS-001

Manufactured for:
PIERSON LABORATORIES, INC.
P.O. BOX 157, SALUDA, NC 28773



300/5524777
17/16

JUN 10 1997

Ms. Marcie Behan
Pierson Laboratories, Inc.
Post Office Box 157
Saluda, North Carolina 28773

Dear Ms. Behan:

SUBJECT: Label Amendment/Design Changes - Chigg Away
EPA Registration Number 36864-1
Your February 26, 1997 Fax

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable subject to the comments listed below. Two copies of the finished labeling must be submitted prior to releasing the product for shipment. A stamped copy is enclosed for your records.

1. We do not object to the additional change, however, "Inert Ingredients" should also be annotated with an asterisk to tie it into the statement on Benzocaine, i.e.,

Inert Ingredients*

Refer to comment 2 of our February 12, 1997 letter. We have not received this information to date.

Sincerely yours,

George T. LaRocca
Product Manager 13
Insecticide/Rodenticide Branch
Registration Division (7505C)

Enclosure



pierson laboratories, inc.

p.o. box 157 saluda, n.c. 28773 704/749-9813
FAX 704/749-9249

TO: George L. Rocca
EPA 703/305-6596

FROM: Marcia Behan

DATE: 2/26/97 NUMBER OF PAGES: 4 (Including cover sheet)

FAX PHONE: 704/749-9249

CONTACT PHONE: 704/749-9813

pierson laboratories, inc.

p.o. box 157
saluda, n.c. 28773

phone: (704) 749-9813
fax: (704) 749-9249

February 26, 1997

Mr. George LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (7505C)

Dear Mr. LaRocca:

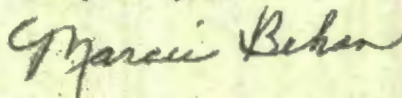
Subject: Label Amendment/Design Changes - Chigg-Away
EPA Reg. No. 36864-1
Your February 12, 1997 letter

Thank you for your quick response for our request regarding a label change. You accepted our label with comments in the above mentioned letter. I am requesting one more change for your approval; that being - *Contains 3% Active Benzocaine for Itch Relief - to be added to the phrase under the Inert Ingredients. The FDA does require the word active for the ingredient benzocaine when claiming itch relief.

I feel sure this will present no problem, but, again wish to have all approvals before ordering plates to be made for new labels. The statement you require under Precautionary Statements will indeed be changed to read "As with all pesticides/drugs..."

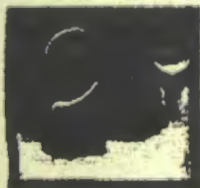
Again, your prompt response to our request is very much appreciated.

Respectfully,



Marcie Behan
President

mlb
Enclosure



Chigg Away

Two Way Action

1-RELIEVES ITCHING due to insect bites, such as chiggers (redbugs), mosquitoes, ticks, fleas, fire ants: minor stings.

2-REPELS chiggers (redbugs)

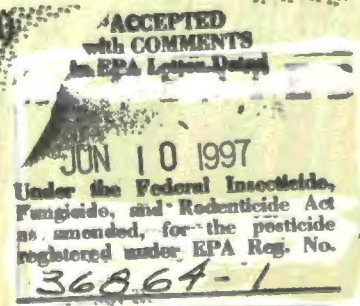
Active Ingredient: Precipitated Sulfur U.S.P. 10.0%

Inert Ingredients: 90.0%

*Contains 3% Active Benzocaine for Itch Relief

**KEEP OUT OF THE REACH OF CHILDREN
SEE BACK PANEL FOR ADDITIONAL
PRECAUTIONS**

NET 4 FL. OZ. (118ML)



6840-01-137-8456

THIS PRODUCT HAS BEEN SEALED FOR YOUR PROTECTION. IF THE IMPRINTED, INNER-FOIL SEAL IS BROKEN OR MISSING, DO NOT USE.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

INDICATIONS: 1-RELIEVES ITCHING and discomfort due to nonpoisonous insect bites such as chiggers (redbugs), mosquitoes, ticks, sand fleas, no-see-ums, biting flies, fire ants, bees and wasps; swimmers itch. **DIRECTIONS:** Apply topically and rub in well as needed. The unique action of CHIGG-AWAY lotion carries prompt relief to the source of irritation. Provides soothing relief from itching. 2-REPELS CHIGGERS (redbugs). **DIRECTIONS:** Apply around feet, ankles, waist and to skin under all areas of tight clothing and around all openings in outer clothing. Reapply after heavy perspiration.

PRECAUTIONARY STATEMENTS: Hazards to Human and Domestic Animals. Caution. For external use only. Keep away from eyes or other mucous membranes. Not for prolonged use. If the condition for which this product is used persists or if a rash or irritation develops, discontinue use and consult a physician. For use on intact skin only. Do not use on children younger than two years. As with all drugs, keep out of the reach of children. In case of accidental ingestion, contact a physician or poison control center at once.

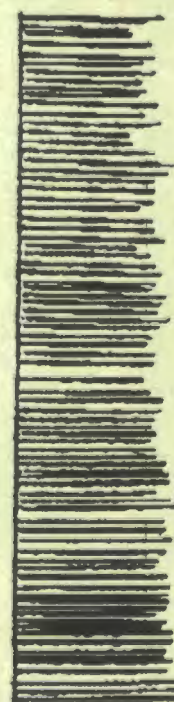
DISPOSAL: Do not reuse bottle. Rinse thoroughly before discarding.

NDC NO: 45591-002-4

EPA REG. NO: 38864-1

EPA EST: 08300-MO-01 or 88669-NC-001

Manufactured for:
PIERSON LABORATORIES, INC.
P.O. BOX 151, SALUDA, NC 28773



8

01898

7 01277

302/5518466
17/15

Ms. Marcie Behan
Pierson Laboratories, Inc.
P.O. Box 157
Saluda, NC 28773

12 FEB 1997

Dear Ms. Behan:

Subject: Label Amendment/Design Changes - Chigg Away
EPA Reg No. 36864-1
Your February 6, 1997 Fax

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable, provided that you make the following changes to the label:

- 1) Please refer to comment 3 and the last paragraph in our January 24, 1996 letter. Under Section 2 of FIFRA benzocaine is not considered an active ingredient and cannot be listed in the active ingredient statement. Since it is also regulated as a drug we discussed its listing on the label with FDA and agreed it could be listed on the label with an asterisk to inert ingredients as indicated in comment 3 of our letter. We would not object to qualifying that phrase to:

*Contains 3% Benzocaine for Itch Relief

- 2) Under Precautionary Statements, revise the statement "As with all drugs..." to "As with all pesticides/drugs..."

Please be reminded also that the previously submitted CSF was not acceptable for reasons identified in our letter of January 24, 1996. An updated CSF should be submitted as soon as possible.

A stamped copy of the label is provided for your records.

Sincerely,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (7505C)

Enclosure

2/12/97

Chigg Away

Two Way Action[®]

1-RELIEVES ITCHING due to insect bites, such as chiggers (redbugs), mosquitoes, ticks, fleas, fire ants: minor stings.

2-REPELS chiggers (redbugs)

Active Ingredients for Repelling Chiggers

Precipitated Sulfur U.S.P. 10%

Active Ingredients for Itch Relief

Benzocaine U.S.P. 3%

Inert Ingredients 87%

**KEEP OUT OF THE REACH OF CHILDREN
SEE BACK PANEL FOR ADDITIONAL
PRECAUTIONS**

NET 4 FL. OZ. (118ML)

ACCEPTED
with COMMENTS
in EPA Letter Dated

12 FEB 1997

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

36864-1

6840-01-137-8456

THIS PRODUCT HAS BEEN SEALED FOR YOUR PROTECTION. IF THE IMPRINTED, INNER-FOIL SEAL IS BROKEN OR MISSING, DO NOT USE.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

INDICATIONS: 1-**RELIEVES ITCHING** and discomfort due to nonpoisonous insect bites such as chiggers (redbugs), mosquitoes, ticks, sand fleas, no-see-ums, biting flies, fire ants, bees and wasps; swimmers itch. **DIRECTIONS:** Apply topically and rub in well as needed. The unique action of CHIGG-AWAY lotion carries prompt relief to the source of irritation. Provides soothing relief from itching. 2-**REPELS CHIGGERS** (redbugs). **DIRECTIONS:** Apply around feet, ankles, waist and to skin under all areas of tight clothing and around all openings in outer clothing. Reapply after heavy perspiration.

PRECAUTIONARY STATEMENTS: Hazards to Human and Domestic Animals. **Caution.** For external use only. Keep away from eyes or other mucous membranes. Not for prolonged use. If the condition for which this product is used persists or if a rash or irritation develops, discontinue use and consult a physician. For use on intact skin only. Do not use on children younger than two years. As with all drugs, keep out of the reach of children. In case of accidental ingestion, contact a physician or poison control center at once.

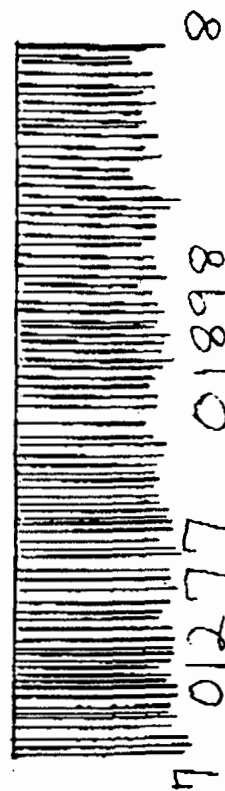
DISPOSAL: Do not reuse bottle. Rinse thoroughly before discarding.

NDC NO: 45591-002-4

EPA REG. NO: 36864-1

EPA EST: 09300-MO-01 or 68669-NC-001

Manufactured for:
PIERSON LABORATORIES, INC.
P.O. BOX 157, SALUDA, NC 28773



5518466



pierson laboratories, inc.

p.o. box 157 saluda, n.c. 28773 704/749-9813
FAX 704/749-9249

TO: George La Roccia
EPA 1-703/305-6596

FROM: Marcia Behar

DATE: 2/6/97 NUMBER OF PAGES: 5 (Including cover sheet)

FAX PHONE: 704/749-9249

CONTACT PHONE: 704/749-9813

pierson laboratories, inc.

p.o. box 157
saluda, n.c. 28773

phone: (704) 749-9813
fax: (704) 749-9249

February 6, 1997

Mr. George LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (7505C)
Environmental Protection Agency
1921 Jefferson Davis Highway
CM#2, Room 200
Arlington, VA 22202

RE: EPA Registration No. 36864-1
Label Design Changes
Your letter January 24, 1996

Dear Mr. LaRocca:

As stated in your letter regarding the labeling changes we needed to make at the time of our next printing, we have complied with the changes you suggested as we prepare for our next label printing. A copy of the front and back labels are attached for your reference.

Before we get much further, however, we need to ask for your consideration again. The FDA has informed us that benzocaine must be an active ingredient for our product since we make the claim "itch relief". You at the EPA tell us that benzocaine is not a repellent and, therefore, must not be listed as an active ingredient. We have certainly found ourselves caught in the middle. In order to satisfy both the FDA and the EPA, I think we have come up with a solution that will work. The company attorney, knowledgeable regarding FDA regulations, feels it is a workable solution. We would certainly hope the EPA is also agreeable.

I am faxing this material to you today and will also put it in the mail for you. If you could contact me with your comments on the proposed label changes, I would be most appreciative.



Mr. George LaRocca

-2-

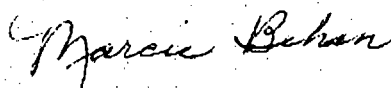
February 6, 1997

Before we consider ordering new artwork, plates, etc. involved in new labels, I would hope that at least a verbal approval at this time while waiting for a written approval is possible.

I realize that our product is unusual and does not fall neatly into one category but I do feel confident that by breaking down the active ingredients for the individual action involved for that ingredient is the answer to the problem.

Your prompt attention to this matter would be greatly appreciated and I will be awaiting your response.

Respectfully,



Marcie Behan
President

mlb

Enclosures

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

24 JAN 1996

300/5499175
355495243
13/13
17/14

Ms. Marcie Behan
Pierson Laboratories, Inc.
PO Box 157
Saluda, NC 28773

Dear Ms. Behan:

Subject: Amendment - Label Design Changes/Add Manufactured; New
Confidential Statement of Formula (CSF)
Chigg Away
EPA Registration No. 36864-1
Your Application Dated May 2, 1995 and Letter FAXed
January 16, 1996

The labeling referred to above, submitted in connection with
registration under the Federal Insecticide, Fungicide, and
Rodenticide Act, as amended, is acceptable, provided that you make
the labeling change bearing the amended labeling:

1. The mis-use statement "It is a violation of Federal Law
to use this product in a manner inconsistent with its
labeling" must follow the Directions for Use heading as
it appeared in the last accepted labeling dated July 11,
1989.

2. Delete the word "Warnings" and replace with the
previously accepted heading:

Precautionary Statements
Hazards to Human and Domestic Animals
Caution

3. Remove "benzocaine" from the active ingredient portion of
the label and list it beneath the ingredient statement
using an asterisk to the total percentage of inert
ingredients i.e.,

Inert Ingredients* 90%




* Contains 3% Benzocaine

If you recall in the Agency's letter of December 28, 1994
regarding the reregistration of products containing benzocaine it
was determined that benzocaine did not meet the definition of a an
active pesticide ingredient as stated in Section 2 of FIFRA. Thus
you were required to change benzocaine from an active to inert
ingredient. Subsequent to the ~~concurrent~~ you called to inform me that

SYMBOL	since benzocaine is a human drug FDA requires it to be listed on				
SURNAME	Hebert				
DATE	1-24-96				

the label. You suggested and we agreed that in order to satisfy both FDA/EPA regulations you would remove benzocaine from the active ingredient section of the label and list it beneath the ingredient statement as indicated above. Once FDA publishes a final monograph establishing the safe and effective use of this drug the product will be deregulated as a pesticide under FIFRA and regulated solely by FDA as a human drug.

The CSF dated for May 2, 1995 is not acceptable for the following reasons:

1. 
 2. Is this CSF for the basic or alternate formulation? You should indicate this in Block A.
 3. Please specify the quantity of each component as actually introduced into the formulation under Column 13a.
 4. The proposed certified limits do not comply with the standard limits specified in 40 CFR 158.175(b)(2).
 5. The upper and lower certified limits for  should be revised so that they are higher and lower, respectively, than the nominal concentration under Column 13b.
 6. The complete chemical compositions are required for the trade name products listed below. The suppliers should be requested to submit the following information for each component in the trade name product: the chemical name; CAS Registry Number; and the percentage in the product. The suppliers may contact EPA directly referencing this EPA Registration Number in their response.
- 

Submit three copies of your final printed labeling before you release the product for shipment. A stamped copy of the labeling is enclosed for your records.

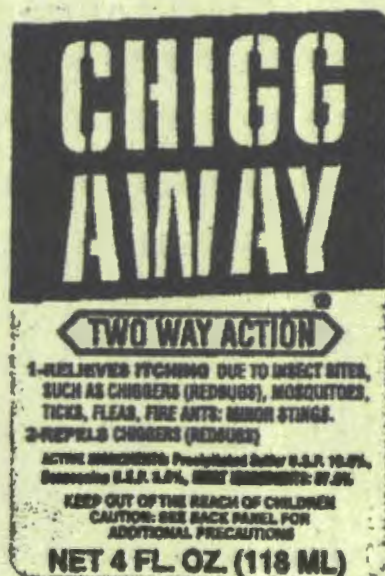
Sincerely yours,

George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (7505C)

Pierson Laboratories, Inc.
P. O. Box 157
Saluda, NC 28773

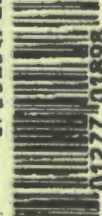
PRODUCT NAME: Chigg-Away

EPA REG. NO: 36864-1



6840-01-137-8456
THIS PRODUCT SHOWN FOR SCALES. IF IMPRINTED UNDER
FOR SEAL IS BROKEN OR MISSING, DO NOT USE

INDICATIONS: 1. **RELIEVES ITCHING** and discomfort due to non-painful insect bites such as chiggers (redbugs), mosquitoes, ticks, and fleas, no two-way action. Use only, hands and wings; customers risk. **DIRECTIONS:** Apply liberally and rub in well as needed. The unique action of CHIGG-AWAY keeps chiggers away from the source of irritation. Provides soothing relief from itching. 2. **REPELS CHIGGERS (redbugs).** **DIRECTIONS:** Apply around feet, ankles, waist and to skin under all areas of tight clothing and around all openings in outer clothing. Reapply after heavy perspiration. **WARNING:** It is a violation of federal law to use this product in a manner inconsistent with its labeling. For external use only. Keep away from eyes or other mucous membranes. Not for prolonged use. If the condition for which this product is used persists or if a rash or irritation develops, discontinue use and consult a physician. For use on infants only. Do not use on children younger than two years. As with all drugs keep out of the reach of children. In case of accidental ingestion contact a physician or poison control center at once. **PRECAUTIONS:** Do not reuse bottle. Flush thoroughly before discarding. **NDC NO:** 6840-01-002-4 **EPA Reg. No:** 36864-1 **EPA EST:** 6840-01-001



PIERSON LABORATORIES, INC.
P.O. Box 157 • Saluda, NC 28773

manufactured for

to be added on next printing

ACCEPTED
with COMMENTS
in EPA Letter Dated

24 JAN 1996

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

36864-1

EPS will be
changed to EPA

CHIGG AWAY

"The Soldier's Choice"

The common belief that chiggers (redbugs) burrow into the skin and suck blood is untrue. A digestive fluid is injected when the mite becomes firmly attached. The itch of the bite is presumably a reaction to the digestive fluid. The myth that you can smother the chigger (redbug) and thereby stop the itch is just that, a myth.

This product is inner foil-sealed. If impunctured inner foil seal is broken or missing, do not use.

CHIGG-AWAY WORKS TWO WAYS

Indications:

1 RELIEVES ITCHING and discomfort due to hypersensitive reaction to such as chiggers (redbugs), mosquitoes, ticks, sand fleas, ro-sars-weat, biting flies, fire ants, bees and wasps; poisonous fish.

Directions: Apply liberally and rub in well as needed. The unique action of CHIGG-AWAY lotion causes prompt relief to the source of irritation. Provides soothing relief from itching.

2 REPELS Chastatoma (chiggers)

Directions: Apply around feet, ankles, waist and to the upper all areas of light clothing and around all openings in outer clothing.

Shampoo after heavy perspiration.

WARNING: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For external use only. Keep away from eyes, nose or other mucous membranes. Not for prolonged use. If the condition for which this product is used persists or if a rash or wheal develops, discontinue use and consult a physician. For use on infants only. Do not use on children younger than two years. As with all drugs, keep out of the reach of children. In case of poisoning, consult a physician or poison control center at once.

NEC NO. 4897-0000-1
EPA Reg. No. 28004-1
EPA Reg. No. 28004-1

Manufactured
for

ACCEPTED
with COMMENTS
in EPA Letter Dated

24 JAN 1996

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

36864-1

will be added
to wording
at next printing

**pierson laboratories, inc.**

p.o. box 157 saluda, n.c. 28773 704/749-9813
FAX 704/749-9249

TO: George La Rocca
EPA

FROM: Marci Behn

DATE: 1/18/96

NUMBER OF PAGES: 4 (Including cover sheet)

FAX PHONE: 704/749-9249

CONTACT PHONE: 704/749-9813

pierson laboratories, inc.

p.o. box 157
saluda, n.c. 28773

phone: (704) 749-9813
fax: (704) 749-9249

January 16, 1996

Mr. George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)
Environmental Protection Agency
1921 Jefferson Davis Highway
CM#2, Room 200
Arlington, VA 22202

RE: Label Amendment

Dear Mr. LaRocca:

Enclosed is our label for our product Chigg-Away which we wish to have approved.

We have made some design changes as well as changes to meet FDA requirements. Your attention to this matter would be much appreciated.

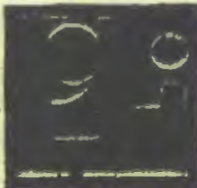
Also, we are still awaiting word on our request in May of 1996 to make changes in our inert ingredients. We look forward to hearing from you regarding this as well.

Sincerely,

Marcella L. Behan

Marcella L. Behan
President

mlb
Enclosure



345-JH-chem

pierson laboratories, inc.

p.o. box 157
saluda, n.c. 28773

phone: (704) 749-9813
fax: (704) 749-9249

May 2, 1995

345/495243

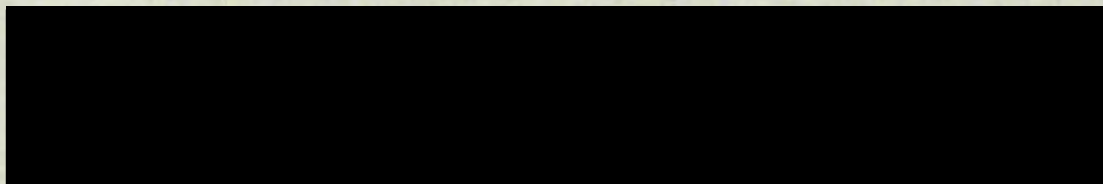
Mr. George T. LaRocca
Product Manager (13)
Insecticide-Rodenticide Branch
Registration Division (TS-767)
Environmental Protection Agency
1921 Jefferson Davis Highway
CM#2, Room 202
Arlington, VA 22202

RE: Registration 36864-1

Enclosed is a new Confidential Statement of Formula. We would like to make some revisions in the inert ingredients and are asking for your approval on these changes.

TAKE OUT

EXCHANGE OR ADD



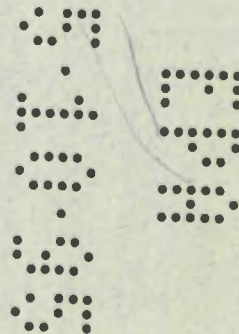
If anything further is needed for an approval, just let me know. Thanks for your help in this endeavor.

Sincerely,

Marcie Behan

Marcie Behan
President

mlb
Enclosure



DATE OUT: OCTOBER 18, 1995

SUBJECT: EP [X] MP [] PRODUCT CHEMISTRY REVIEW
DP BARCODE No.: D220043 REG./File Symbol No.: 36864-1
PRODUCT NAME: CHIGG AWAY
COMPANY: PIERSON LABORATORIES, INC.

TO: John Hebert, PM Team 13
Insecticide-Rodenticide Branch
Registration Division (7505C)

FROM: Michael J. Clifford, Chemist *mjc 10/18/95*
Product Chemistry Review Section
Registration Support Branch/RD (7505W)

THRU: Harold Podall, Section Head
Product Chemistry Review Section
Registration Support Branch/RD (7505W) *HA 10/18/95*

SUMMARY OF FINDINGS:

BACKGROUND: A revised CSF was submitted presumably for the basic formulation which changes some of the inert ingredients.

CONCLUSIONS:

1. The revised CSF dated 5/2/95 is not acceptable based on the following considerations:

a. The source product for precipitated sulfur, EPA REG. No.

b. In Block A, please check the appropriate block to indicate whether the CSF refers to a basic or an alternate formulation.

c. Please specify the quantity of each component as actually introduced into the formulation under Column 13a.

d. Please provide an explanation of the basis for your proposed certified limits for the active and most of the inert ingredients since they do not comply with the standard limits specified in 40CFR §158.175(b)(2).

e. The upper and lower certified limits for the [REDACTED] identified in Confidential Apperdix A should be revised so that they are higher and lower, respectively, than the nominal concentration listed under Column 13b.

f. The complete chemical compositions are required for the [REDACTED] identified in Confidential Appendix A.

7505W:RD:RSB:PCRS:MJCLIFFORD:mjc:10/18/95:703-308-8372:36864-1

CONFIDENTIAL APPENDIX A

DATE OUT: OCTOBER 18, 1995

PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]
DP BARCODE No.: D220043 REG./File Symbol No.: 36864-1
PRODUCT NAME: CHIGG AWAY
Reviewer: MJCLIFFORD Company: PIERSON LABORATORIES, INC.

1. In reference to CSF dated 5/2/95:

a. The upper and lower certified limits for [REDACTED]
(Preservative) should be revised so that they are higher and lower,
respectively, than the nominal concentration of [REDACTED]

b. The complete chemical compositions are required for the
following trade name products since there is no information
currently in the suppliers' master files:

[REDACTED]

The suppliers should be requested to submit the following
information for each component in the trade name product:
the chemical name; CAS Registry Number; and the percentage in the
product. The suppliers may contact EPA directly referencing this
EPA file symbol in their responses.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION
INSECTICIDE-RODENTICIDE BRANCH

Fax Number (703) 305-6596

F A C S I M I L E R E Q U E S T / C O V E R S H E E T

(Please type or print in BLACK INK only)

S E N D F A X T O :

NAME: Robert Estelman

OFF: OTC Compliance Branch

FAX PHONE NUMBER: (301) 594-0165

OFFICE PHONE NUMBER: (301) 594-1065

F R O M :

NAME: George LaRocca

DIVISION/BRANCH: RD/IRB

OFFICE PHONE NUMBER: (703) 305-6120

OFFICE ROOM NUMBER: 204

MAIL CODE: 7505C DATE: 11/30/95 TIME: 3:45

NUMBER OF PAGES (WITH COVER SHEET): 4

S p e c i a l M e s s a g e - - - d e s c r i b e b e l o w :

Bob: As discussed attached is a copy of the "Chigg Away" label (best copy in file) containing sulfur and benzocaine and a copy of EPA letter regarding the re-registration eligibility decision for benzocaine. I informed our re-registration group that since benzocaine is an OTC drug (old human drug) it must be declared on the label to meet FDA requirements. Upon receipt of our 12/28/94 letter Tom Behan (Person Labs) called and asked if he could list benzocaine beneath the ingredient statement i.e. "Contains 3% benzocaine" rather than list it in the active ingredient statement. Thus in his opinion he would still be in compliance with FDA and EPA would no longer consider it a pesticide. Your comment(s) are appreciated.

George



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DEC 28 1994

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Thomas E. Behan
Pierson Laboratories Inc.
Box 157
Saluda NC 28773

RE: The Reregistration Eligibility Decision (RED) for benzocaine,
Chemical #97001, Case #4012; EPA Registration #36864-1 (Chigg Away)

Dear Mr. Behan:

Through this letter, the Agency is announcing its decision on the reregistration eligibility of the chemical benzocaine. The Agency determined during the Reregistration Phase 4 process that the chemical benzocaine does not meet the definition of an "active ingredient" as stated in Sec. 2 of FIFRA, that is, it does not prevent, destroy, repel or mitigate any pest. As a result of this determination the Agency has decided to "deregulate" benzocaine.

Your product {EPA Registration #36864-1 (Chigg Away)} will continue to be regulated by EPA since sulfur is a pesticidally active ingredient that is used in the product to repel chiggers (redbugs). As you know a Reregistration Eligibility Decision has already been issued for sulfur covering your product.

Because of this decision to deregulate benzocaine, you are required to submit an amended label and Confidential Statement of Formula (CSF) changing benzocaine from an active ingredient to an inert ingredient. Please submit this information to George Larocca in the Registration Division.

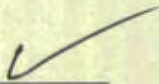
If you have any questions regarding this letter please contact Barbara Briscoe in the Planning and Reregistration Branch on (703) 308-8177.

Sincerely,

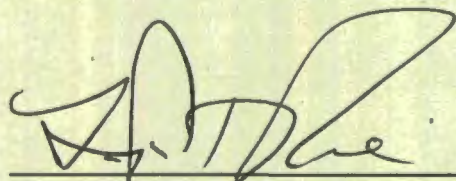
Peter P. Caulkins, Acting Director
Special Review and
Reregistration Division

"The active ingredient known as benzocaine and identified as case 4012 on Reregistration List D is hereby "deregulated" because it does not meet the definition of an active ingredient as stated in Sec. 2 of FIFRA. Benzocaine does not prevent, destroy, repel or mitigate any pest. Benzocaine is regulated as a medicine by FDA. The one product currently registered containing benzocaine as an itch reliever also contains sulfur as an active ingredient. The product will continue to be regulated by EPA as sulfur is the active ingredient used in the product to repel chiggers (redbugs). This action deregulating benzocaine effectively removes it from the Agency's reregistration program."

Approve



Disapprove



Date

12/23/94

Louis P. True, Jr., Acting Director
Special Review and Reregistration Division

(301) 594-0165

ROUTING AND TRANSMITTAL SLIP

Date

TO: (Name, office symbol, room number,
building, Agency/Post)

Initials

Date

1.		
2.		
3.		
5.		

Action	File	Note and Return
Approval	For Clearance	Per Conversation
As Requested	For Correction	Prepare Reply
Circulate	For Your Information	See Me
Comment	Investigate	Signature
Coordination	Justify	

REMARKS

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)

Room No.—Bldg.

Phone No.

8041-102

OPTIONAL FORM 41 **56**. 7-76)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

54

10/8

Before you QC sites as requested
in attached memo verify ~~site~~

1/1 This is only product containing
benzo came, Yes according to
REFS.

2/ Since it is a drug/pesticide
product eventually to be
regulated solely by FDA
call FDA on drug
status of this chemical. ?

Have they completed monograph.

Do they intend to? When?

See May 28, 1980 ltr for
background.

3/ This product also contains sulphur,
for which a RFD has already
been issued. Are they in
compliance. See Bob Rose

Human Drug (OTC)

301-295-8065 Bob Eschelman
Bob Heller / Eschelman 57

no
Final
monograph
#proposed
rule
2/5/83
Vol. 40
no. 27
P. 5852
5869

OK

10/15/92

REGISTRATION DIVISION LUIS SITE VERIFICATION FORM

CASE NO. 4012 CHEMICAL NO. 097001

Please compare the sites in the LUIS General Report to those for this chemical in your Jacket files so that it is assured all sites have been included. Note your response below. Additionally, if the sites in your Jackets for this chemical do not reflect those in REFS, use the F10 Key to note the error. The Information Services Branch resolves these on a weekly basis.

1) Are the sites, which are reflected in the LUIS Report, a correct representation of those contained in your Jackets for this chemical?

Yes ☒ No ()

2) If NO, list those sites and labels that were not reflected in the LUIS Reports for this Chemical:

3) List any other comments you have on this Chemical or Report:

Margaret - This product is a drug/pesticide so eventually it will be solely →

PM REPORTING ON CHEMICAL (NAME, MAIL CODE & PHONE)

Please fill in:

GEORGE CAROCCA, H7505C 305-6100

Please fold over, tape and send back to the LUIS staff within the time frame specified in the cover letter. If you need more time, please contact the LUIS staff listed in this cover letter. Thanks for your assistance.

DATE OF REQUEST: / /

CONTACT:

JOHN HERBERT

305-5419

(H7503W)

CS-#1 4TH FLOOR

BIOLOGICAL ANALYSIS BRANCH/HEAD

TO: LUIS STAFF

SUBJECT: RD SITE VERIFICATION

regulated by FDA. They have not published a final monograph (loosely, FDA's version of EPA's Registration Standard for a drug/~~Chemical~~ Chemical) on benzocaine. A proposed rule was published 2/8/83 (FR notice Vol. 48 no. 27 p. 5852-5869). Also the subject ~~and~~ product contains sulfur which is under a RED. So far registrant has complied with Sulfur RED. Let me know if you need ~~any~~ more information. John Hebert
 a 305-5419 (your Reaping friend)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 6, 1992

MEMORANDUM

SUBJECT: Registration Division's Quality Control of Use Patterns
in LUIS Reports

FROM: Margaret A. Cogdell *Margaret A. Cogdell*
LUIS Project
Biological Analysis Branch/BEAD

TO: Herbert Harrison, Chief
Insecticide-Rodenticide Branch

The Registration Division management requested that the LUIS staff allow the RD/PM the responsibility of QCing sites for the chemical under reregistration review before reports are distributed to the OPP scientists.

Included in the analysis of each chemical, the PM(s) should compare the sites in the LUIS general report to those for the specific chemical in their jacket files, so that it is assured that all sites have been included. In addition, if the sites in your jackets for the particular chemical do not reflect those in REFS, then corrections should be made by using the F10 key. The Information Services Branch are responsible for resolving these issues on a weekly basis.

Attached please find a "Use Group/Site" report for each of the following chemical(s):

0011-086003	Warfarin, sodium salt - 14
4012-097001	Ethyl-p-aminobenzoate benzocaine 13
4117-486300	Hydroprene - 18

We would appreciate you reviewing the attached report(s) and returning comments to us within five days (per chemical) after receipt of the report(s). Please return your comments to Margaret Cogdell (308-8108) of the Biological Analysis Branch/BEAD (H7503W).

Thank you for your assistance.



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10/08/92

REFERENCE FILES SYSTEM

PAGE 1

ACTIVE PRODUCTS CONTAINING THE ACTIVE INGREDIENT 097001

Ethyl para-aminobenzoate

PERCENT	IDENT. NO.	STATUS	FORM CODE	PRODUCT NAME
03.0000	36864-1	A	16	CHIGG AWAY

097001 - Ethyl-p-aminobenzoate benzocaine

LUIS
General Chemical Report
Type(s) of Pesticide

(DYNAMAC REPORT)

Date: 23 SEP 1992
Page: 1

Description.....

REPELLENT/FEEDING DEPRESSANT

LUIS
General Chemical Report
Factoring Terms for Selected Compounds
at Product Level

(DYNAMAC REPORT)

Date: 23 SEP 1992

Page: 1

Reg.No.....	AI Percent.	AI Codes	AI Den	Fctrng Term	.. Fctrng%...	.. Ttl Fctrng%	Fctrng Den	Ttl Fctrng Den	Ttl Den	. Ttl Prod Conc.....
036864-00001	10.0000	077501								10 lb gal
	3.0000	097001								

LUIS
General Chemical Report
Use Groups

(DYNAMAC REPORT)

Date: 23 SEP 1992
Page: 1

Use Group. Description.....

INDOOR RESIDENTIAL

01

LUIS
General Chemical Report
Site and Use Groups

(DYNAMAC REPORT)

Date: 23 SEP 1992
Page: 1

Site.....	Use Group.....	Use Group Category Desc..
-----------	----------------	---------------------------

HUMAN BODY/CLOTHING WHILE BEING WORN (INSECT CONTROL)		
---	--	--

INDOOR RESIDENTIAL		
--------------------	--	--

Non-Food/Non-Feed Uses		
------------------------	--	--

Reg.No..... Iss.Cat. Description..... Site..... Use Group..... Application Type..... Application Timing..... Application Equipment....

036864-00001 G No pest coding included with
 this product.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

~~305-2253-598~~
38/8

OCT 13 1989

Mr. Thomas E. Behan
Pierson Laboratories, Inc.
P.O. Box 157
Saluda, NC 28773

Dear Mr. Behan:

Subject: Review of Efficacy Data
Chigg-Away
EPA Registration No. 36864-1
Your Letter Dated July 20, 1989

The submitted data do not support the addition of ticks to the label. While laboratory data look promising, field data (which are minimal, only two total subjects) indicate poor performance. An average of only 46 percent repellency as compared to untreated controls was achieved. As only two subjects were used, data may be overridden by studies incorporating larger numbers of subjects. To support a general claim for ticks, studies on both American Wood Tick Dermacentor variabilis and Lone Star Tick Amblyomma americanum should be submitted.

Sincerely yours,

George T. LaRocca
George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (H7505C)

55355:I/C:Herbert:LLR-1:KENCO:10/05/89:11/20/89:DD

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

67

PM TEAM 17 PRODUCT PERFORMANCE REVIEW

PM: 15

09-20-89

36864-1
Chigg Away
Pierson Laboratories
Saluda, NC 28773

IN: 09-14-89
DUE: ASAP
AC: 305
RN: -----
MRID: na

254813

FORMULATION

Sulfur..... 10.000%
Benzocaine..... 3.000
RTU

benzocaine-analgesic ingredient

INTRODUCTION

Data submitted addition of ticks to the label.

USES

Product is as a topical preparation to repel chiggers on humans.

SUBMITTED DATA

No MRID assigned.

1. Mount, G.A. 1979. Personal protection against lone star tick attack with topical applications of 10 sulfur lotion. Unpublished.

2 subjects used round-robin in wooded pastures in Oklahoma. Total numbers of lone star ticks Amblyomma americana, after a 1 hour exposure. Untreated comparison but no positive control. Three series were completed, results as follows:

<u>Series</u>	<u># Attached Ticks</u>	<u>% Redux. vs Untreated</u>
1	21	80
2	50	34
3	47	0
Average	39	46
UTC	72	

2. Hair, J.A. 1978. (Dr. Hair is with the OK ST U., it is not known whether the document is from the Dept. of Ent. or personal)

Chigg Away was used as a 1:1, 1:10, and 1:100 dilution with an unspecified diluent (white out used) to the entire body of guinea pigs. 2 treated, 2 untreated. Each was exposed 40 lone star tick nymphs, by placing the animal in a paper bag containing the ticks. As the diluent is unknown, only the 1:1 results are reported here.

<u>Group</u>	<u>No. attached ticks:</u>			
	<u>Day 1</u>	<u>Day 2</u>	<u>Day 3</u>	<u>Day 7</u>
ChiggAway	0	6	4	24
Untreated	32	30	17	23
% Reduction	100	80	76	0

CONCLUSIONS

1. The submitted data do not support the addition of ticks to the label. While ~~the~~ laboratory data look promising, ~~the~~ field data (which are minimal, only 2 total subjects) indicate poor performance. An average of only 46% repellency as compared to untreated controls was achieved. As only 2 subjects were used, ~~the~~ data may be overridden by ~~the~~ submission of studies incorporating larger numbers of subjects. To support a general claim for ticks, studies on both ~~the~~ American Wood Tick Dermacentor variabilis and ~~the~~ lone star tick Amblyomma americanum should be submitted.

Phil Hutton
PM 17

**pierson laboratories, inc.**

p.o. box 157

saluda, n.c. 28773

704/749-9813

704/749-9249

July 20, 1989

Mr. Phil Hutton
Insecticide-Rodenticide Branch
Registration Division (H-5707C)
Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA. 22202

Re: EPA Registration No. 36864-1

Dear Mr. Hutton:

We are going to try to get ticks added to the label. Would you please get us an efficacy report on the two tick tests enclosed. These tests were done with our Chigg-Away formulation, EPA Number 36864-1

Your attention to this matter will be greatly appreciated.

Sincerely,

Thomas E. Behan
Vice President

TEB/mlb
Enclosures

Report 1/ by

Gary A. Mount
Lone Star Tick Laboratory
USDA, SEA, AR
P.O. Box 588
Poteau, OK 74953

1/ This report is not a publication and should not be referred to in literature citations. This report should not be used in sales promotions or advertising which expresses or implies endorsement of a product by the U.S. Department of Agriculture.

AND CONSULTING
510 Ute Drive
Stillwater, OK 74074
July 3, 1978

Mr. Jack Pierson, Jr.
Pierson Enterprises
5908 Reinhardt Drive
Shawnee Mission, KS 66203

Dear Mr. Pierson:

Attached is the letter-type report resulting from my preliminary observations on Chigg Away[®] against lone star ticks.

Honestly, the results were extremely surprising and I would think further testing of the potential as a repellent might be in order.

I have enjoyed being of service.

Best regards.

Sincerely,

J. Alexander Hair, PhD
Research Consultant

Attachment

cc: Mr. Tom Behan, 11304 Dunbrook, Richmond, VA 23235
Dr. Norman Lau, 17 Laurel Lane, Blacksburg, VA 24060

JAH/sh

Dear Tom

for E. perousei - the
DR. Donald E. Waller's *Science* article ticks
necessity should pose no problem in *Science*
Additional tick data in on present EPA
two other opms from Entomologists Concernant *Science* *Conclusions*



United States Environmental Protection Agency
Office of Pesticide Programs
Washington, DC 20460

Data Review Record

Confidential Business Information - Does not contain
National Security Information (E.O. 12065)

Pack Number

Date Received

1. Product Name

Chiss-Away

Chemical Name

Benzocaine

2. ID

Identifying Number

26864-1

3. ID

Record Number

251,550

4. Action

Code

305

5. MRID/

Accession Number

6.

Study Guideline or Narrative

7. Reference No.

8

8. Date Rec'd (EPA)

9/14/89

9. Prod/Review Mgr/DCI

La Rocca/OZ

10. PM/RM Team No.

15

11. Date to HED/
EFED/RD/BEAD

9/14/89

12. Proj Return Date

10/14/89

13. Date Returned
to RD/SRRD

Instructions

additicks to label.

This Section Applies to Review of Studies Only

14. Check Applicable Box

☐

Adverse 6(a)(2) Data (405)

☐

Generic Data (Reregistration) (660)

☐

Special Review Data (870)

☐

Product Specific Data (Reregistration) (655)

16. Have any of the above studies (in whole or in part) been previously submitted for review?

☐

Yes (Please identify the study(ies))

☐

No

15. No. of Individual Studies
Submitted

17. Related Actions

18.

To

Type of Review

19. Reviews Also Sent to

20. Data Review Criteria

HED

Science Analysis & Coordination
Toxicology/HFA
Toxicology/IR
Dietary Exposure
Nondietary Exposure

SAC ☐ PC
TOX/HFA ☐ PL
TOX/IR ☐
DEB ☐ EA
NDE ☐ AC
☐ BA

A. Policy Note No. 31

☐ 1 = data which meet 6(a)(2) or
meet 3(c)(2)(B) flagging
criteria

EFED

Ecological Effects
Environmental Fate & Groundwater

EEB ☐
EFGWB ☐

☐ 2 = data of particular concern
from registration standard

SRRD

Special Review
Reregistration
Generic Chemical Support

SR ☐
RER ☐
GSC ☐

☐ 3 = data necessary to determine
tiered testing requirements

RD

Insecticide-Rodenticide - Efficacy OBS
Fungicide-Herbicide DMH
Antimicrobial 9/20/89
Product Chemistry
Precautionary Labeling

IR ☐
FH ☐
AM ☐

B. Section 18

☐ 1 = data in support of section 3
in lieu of section 18

BEAD

Economic Analysis
Analytical Chemistry
Biological Analysis

C. Inert Ingredients

☐ 1 = data in support of continued
use of List 1 inert

☐ Confidential Statement of Formula
(EPA Form 8570-4) Attached (Trade Secrets)

☐ Label Attached

EPA Form 8570-17 (Rev. 11-88)
Previous editions are obsolete.

White - Data Coordinator
Yellow - Data Review Section

Pink - PM/RM/DCI
Green - Return with completed review

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Gene Clark

300 / 232220
17 17

JUL 11 1989

Mr. Thomas E. Behan
PLI Pierson Laboratories, Inc.
P. O. Box 157
Saluda, NC 28733

Dear Mr. Behan:

Subject: Amendment - Update Labeling
Chigg-Away
EPA Registration No. ~~38664-1~~ *36864-1*
Your Application Dated December 3, 1987

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records.

I note that on July 5, 1989 Art Donner of our Administrative Processing Section notified you that he will take the necessary steps to reinstate this product to full active registration status.

Sincerely yours,

George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division

Enclosure

RD:G:LaRocca:CG:7:10:89

CONCURRENCES

SYMBOL							
SURNAME							
DATE							



FA (301) 594-0165

pierson laboratories, inc.

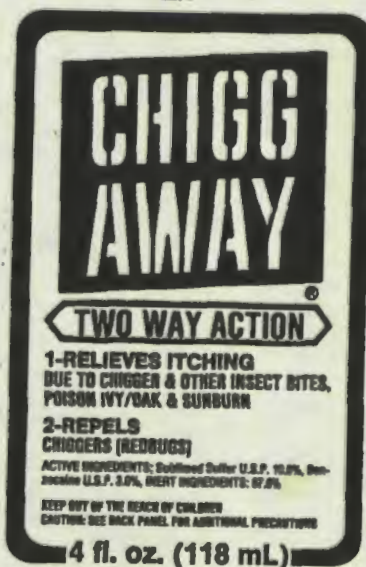
P. O. BOX 157

SALUDA, NC 28773

704/749-9813

PRODUCT NAME: Chigg-Away

EPA REG. NO.: 36864-1



6505-01-137-8456

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with the labeling.

1-EFFECTIVELY RELIEVES ITCHING and discomfort of all non-poisonous insect bites such as chiggers (redbugs), mosquitoes, ticks, sand fleas and biting flies; also relieves itching of poison ivy/oak and sunburn. The unique action of Chigg-Away lotion carries prompt relief to the source of irritation. Provides soothing relief from itching. Apply topically and rub in well as needed.

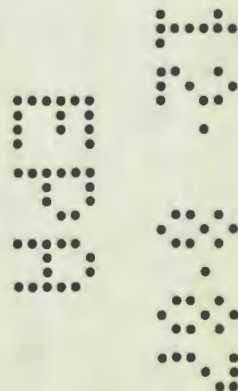
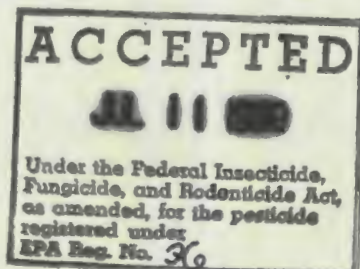
2-EFFECTIVELY REPELS CHIGGERS (redbugs). Apply around feet, ankles, waist and to skin under all areas of tight clothing and around all openings in outer clothing. Reapply after heavy perspiration.

PRECAUTIONARY STATEMENTS: For External Use Only. Keep away from eyes or other mucous membranes. Not for prolonged use. If the condition for which this preparation is used persists or if a rash or irritation develops, discontinue use and consult physician. Use on intact skin only. Not to be used on infants younger than two years.

DISPOSAL: Do not reuse bottle. Rinse thoroughly before discarding.

NDC No. 45391-04
EPA Reg. No. 36864-1
EPA Est. 09300-MO-01

Manufactured for
PIERSON LABORATORIES, INC.
P.O. Box 157 • Saluda, NC 28773
By L.J. YORK CO.
P.O. Box 60 • Bucklin, MO 64631





300-00
232220

pierson laboratories, inc.

~~PO BOX 1007~~ ~~Saluda, NC 28584~~ ~~704/749-8980~~
~~704/272-7818~~

P. O. BOX 157

SALUDA, NC 28773

704/749-9813

December 3, 1987

Mr. George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)
Environmental Protection Agency
1921 Jefferson Davis Highway
CM#2, Room 200
Arlington, VA 22202

Re: EPA Registration No. 36864-1

Dear Mr. LaRocca:

Enclosed is our label for our product Chigg-Away which we wish to have approved.

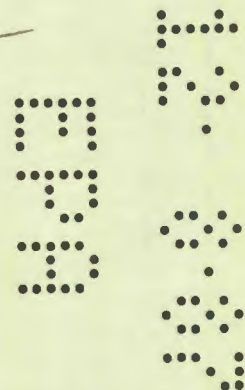
We had a new label printed because of an address change. However, the changes you requested in your letter of Oct. 15, 1986, have been incorporated in this printing.

We appreciate your attention to this matter.

Respectfully,

Thomas E. Behan
Vice President

TEB/mlb
Enclosure



REFERENCE REQUEST—FEDERAL RECORDS CENTERS

NOTE: Use a separate form for each request.

SECTION I—TO BE COMPLETED BY REQUESTING AGENCY

RECORD GROUP NO.	ACCESSION NO.	AGENCY BOX NUMBER	RECORDS CENTER LOCATION NUMBER
412	890004	OF 06	11/48:55-6.1
DESCRIPTION OF RECORD(S) OR INFORMATION REQUESTED (Include file number and title.) EPA REGISTRATION JACKET (CANCELLED) 36864-1			

REMARKS

THESE JACKET ARE BEING RETREIVED BY GEORGE IAROCCA RD/OPP

NATURE OF SERVICE

<input type="checkbox"/> FURNISH COPY OF RECORD(S) ONLY	<input type="checkbox"/> PERMANENT WITHDRAWAL	<input checked="" type="checkbox"/> TEMPORARY LOAN OF RECORD(S)	<input type="checkbox"/> REVIEW	<input type="checkbox"/> OTHER (Specify)
NAME OF REQUESTER Webster/L. Jones		TELEPHONE NO. 557-3240	DATE 06/13/89	RECEIPT OF RECORDS
NAME AND ADDRESS OF AGENCY (Include street address, building, room no. and ZIP Code) ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDE PROGRAMS (TS-757C) PMSD, INFORMATION SERVICES BRANCH 401 M. Streets, S.W. CM#2 RM. 220 Washington, D.C. 20460		Requester please sign, date and return this form, for file item(s) listed above, ONLY if the block to right has been checked by the Records Center. SIGNATURE _____ DATE _____		

SECTION II—FOR USE BY RECORDS CENTER

REMARKS			
<input type="checkbox"/> RECORDS NOT IN CENTER CUSTODY <input type="checkbox"/> RECORDS DESTROYED			
<input type="checkbox"/> WRONG BOX NUMBER—PLEASE RECHECK			
<input type="checkbox"/> ADDITIONAL INFORMATION REQUIRED TO IDENTIFY RECORDS REQUESTED			
<input type="checkbox"/> MISSING (Neither record(s), information nor charge card found in container(s) specified)			
<input type="checkbox"/> RECORDS PREVIOUSLY CHARGED OUT TO (Name, agency and date):			
DATE 6-29-89	SERVICE	TIME REQUIRED	SEARCHER'S INITIALS JL

SECTION III—TO BE COMPLETED BY REQUESTING AGENCY

General Services Administration
Federal Records Center NARS
REFERENCE BRANCHTO
SUITLAND, MARYLAND
(City) (State)STOP 386
(Zip Code)NOTE: In Washington, D.C. area
send to STOP 386

ROUTING AND TRANSMITTAL SLIP

Date

7/5/89

TO: (Name, office symbol, room number,
building, Agency/Post)

Initials

Date

1. George LaRocca RM 15

2. H7505C Rm 204

3.

4.

5.

Action	File	Note and Return
Approval	For Clearance	Per Conversation
As Requested	For Correction	Prepare Reply
Circulate	For Your Information	See Me
Comment	Investigate	Signature
Coordination	Justify	

REMARKS

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)

Room No.—Bldg.

Phone No.

Art Donner

5041-102

OPTIONAL FORM 41 (Rev. 7-78)
Prescribed by GSA
FPMR (41 CFR) 101-11.606

GPO : 1987 0 - 196-409

82



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

**COPY FOR YOUR
INFORMATION**

JUL 5 1989

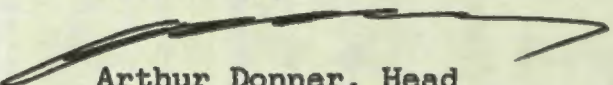
OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Mr. Thomas E. Behan
Pierson Laboratories, Inc.
P.O. Box 157
Saluda, NC 28773

Dear Mr. Behan:

This letter is in response to your inquiry letter dated June 13, 1989. After researching our records, I have determined that EPA incorrectly cancelled your product registration 36864-1 with the product name Chigg Away. I have take the necessary steps to reinstate this product registration to full active status. Thank you for bringing this matter to my attention.

Sincerely,


Arthur Donner, Head
Administrative Processing Section
Registration Support Branch
Registration Division (H7505C)

cc. George T. LaRocca (PM-15)

OCT 15 1986

200/172394
17/6

Mr. Thomas E. Behan
Pierson Laboratories, Inc.
P.O. Box 1097
Swansboro, NC 28584

Dear Mr. Behan:

Subject: Amendment - Label Revision
Chigg-Away
EPA Registration No. 36864-1
Your Letter Dated April 14, 1986

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records.

Make the following label changes in the next printing of your label.

1. Change the active ingredients to

Sulfur	10.0%
Benzocaine	3.0%

2. The words ACTIVE INGREDIENTS and INERT INGREDIENTS must be printed in type of the same size.
3. The child hazard warning KEEP OUT OF REACH OF CHILDREN with the signal word CAUTION immediately below should appear on the front label.
4. Add "DIRECTIONS FOR USE" followed with "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

86169:Newkirk:LR-12:KENCO:8/11/86:8/20/86:TAR:lmf

CONCURRENCES

SYMBOL ▶							
SURNAME ▶	AS/K.V.I.						
DATE ▶	8-18-86						

5. Delete "WARNING: Keep this and all drugs out of reach of children."
6. Add a heading PRECAUTIONARY STATEMENTS and assemble the precautionary sentences.

Sincerely yours,

George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

Enclosure

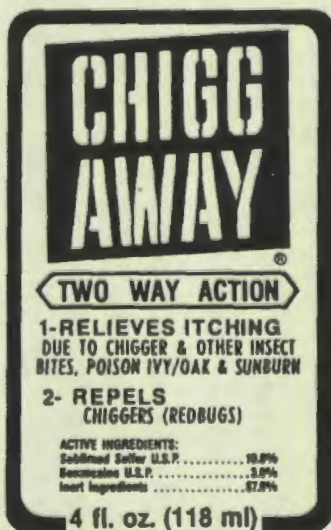
Pierson Laboratories, Inc.
EPA Registration Number: 36864-1

REGISTERED
WITH COMMENTS
in EPA Letter Dated

OCT 15 1986

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

36864-1



CHIGG-AWAY WORKS TWO WAYS

1-EFFECTIVELY RELIEVES ITCHING and discomfort of all non-poisonous insect bites such as chiggers (redbugs), mosquitoes, ticks, sand fleas and biting flies; also relieves itching of poison ivy/oak and sunburn. The unique action of Chigg-Away lotion carries prompt relief to the source of irritation. Provides soothing relief from itching. Apply topically and rub in well as needed.

2-EFFECTIVELY REPELS CHIGGERS (redbugs). Apply around feet, ankles, waist and to skin under all areas of light clothing and around all openings in outer clothing. Reapply after heavy perspiration.

CAUTION: For External Use Only. Keep away from eyes or other mucous membranes. Not for prolonged use. If the condition for which this preparation is used persists or if a rash or irritation develops, discontinue use and consult physician. Not to be used on infants younger than two years.

WARNING: Keep this and all drugs out of reach of children. In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.

DISPOSAL: Do not reuse bottle. Rinse thoroughly before discarding.

NDC No. 45281-04
EPA Reg. No. 36864-1
EPA Est. 88386-MO-81
Pat. Pend.

Manufactured for
PIERSON LABORATORIES, INC.
P.O. Box 1097
Swansboro, NC 28584
By L.T. YORK CO.
Brookfield, MO 64628





300 09

pierson laboratories, inc.

p.o. box 1097

swansboro, nc. 28584

919/326-3933
804/272-7313

April 14, 1986

Mr. Richard Newkirk
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (TS767)
Environmental Protection Agency
1921 Jefferson Davis Highway
CM#2, Room 200
Arlington, VA 22202

Re: EPA Registration No 36864-1

Dear Mr. Newkirk:

Enclosed is our label for our 4 ounce bottle which we wish to have approved. Other than changing from 2 ounce to 4 ounce and adding relief of poison ivy/oak and sunburn, it is pretty much the same.

Thanks for your attention to this matter.

Sincerely,

Thomas E. Behan
Vice President

TEB/mlb
Enclosure



JAN 27 1986

Mr. Thomas E. Behan
Pierson Laboratories, Inc.
P.O. Box 1097
Swansboro, NC 28584

Dear Mr. Behan:

Subject: Amendment - Updated Formula Source of Sulfur
Chigg-Away
EPA Registration No. 36864-1
Your Application Dated July 18, 1985

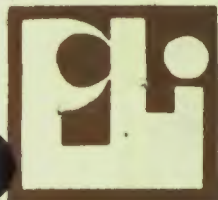
The source of the registered technical sulfur is acceptable. This
information has been made a part of the registration record for this product.

Sincerely yours,

George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

50457:LaRocca:IR-5:KEMCO:1/23/86:1/31/86:eg:VO

CONCURRENCES							
NAME	DATE						
NEULIRK	7-27-86						



pierson laboratories, inc.

p.o. box 1097

swansboro, nc. 28584

919/326-3933

804/272-7313

July 18, 1985

Mr. George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (TS-767)
Environmental Protection Agency
1921 Jefferson Davis Highway
CM#2, Room 200
Arlington, VA 22202

re: Registration Application - Nov. 5, 1984
for Chigg-Away
EPA Registration No. 36864-1

Dear George:

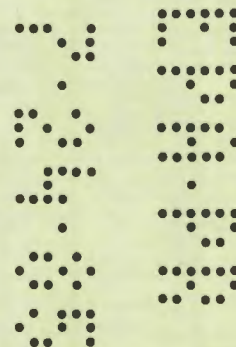
[REDACTED]

Hope things are going fine for you. If you need any further information from us, please give me a call.

Sincerely,

Thomas E. Behan
Vice President

TEB/mlb
Enclosures



REGISTRATION DIVISION DATA REVIEW RECORD

Confidential Business Information - Does Not Contain National Security Information (E.O. 12065)

9/3
CL

CHEMICAL NAME

IDENTIFYING NUMBER

Action Code

RECORD NO. / REFERENCE NO.

TO BE COMPLETED BY PM

36864-1

346

157321/5

DATE RECEIVED (EPA)

7/24/85

PRODUCT MANAGER (PM)

LaRocca

PM TEAM NUMBER

15

DATE SENT TO

TSS

8/28/85

PRIORITY NUMBER

☒ Review Requires Less Than 4 Hours

INSTRUCTIONS TO REVIEWER

TSS/RD

RELATED ACTIONS

3(c)(1)(D)

- ☐ Use Any or All Available Information ☐ Use Only Attached Data
☐ Use Only the Attached Data for Formulation and Any or All
☐ Available Information on the Technical or Manufacturing Chemical.

REVIEWS SENT TO

☐ EF

☐ PL

☐ CH

To

TYPE OF REVIEW

NUMBER OF ACTIONS

Registration

Petition

EUP

SLN

X CHEMISTRY

10/31/85
NAR / EDC

1

EFFICACY

PRECAUTIONARY LABELING

☐ Label Submitted
with Application
Attached

☐ Confidential
Statement of
Formula

☐ Representative
Labels Showing
Accepted Uses
Attached

APR 29 1985

Thomas Behan
Pierson Laboratories, Inc.
P.O. Box 1097
Swansboro, NC 28584

345/140435
13/5

Dear Mr. Behan:

Subject: Conditional Registration Application
Amendment - Updated Formula Source of Sulfur
Chigg-Away
EPA Registration No. 36864-1
Your Application Dated November 5, 1984

This will acknowledge receipt of the revised formula and technical brochures relating to the source of sulfur for the subject product. This information has been reviewed by the Agency and we have no real objections to your submission. However, you must identify in more specific terms the sources of sulfur you will be utilizing. We note that certain coarse grades of sulfur would not be acceptable for use in this product.

In regard to the above, when identifying the source of sulfur, unless you identify that you are using a registered source for the sulfur, your amendment request cannot be approved as submitted. Your options are as follows:

1. Cite as your source of sulfur a registered technical. The Agency has identified three such possible sources, Landia Chemical Company, P.O. Box 366, Lakeland, FL 33802, EPA Registration No. 9859-126; FMC Corporation, Agriculture Chemicals Division, 2000 Market Street, Philadelphia, PA 19103, EPA Registration No. 279-242; Georgia Gulf Sulfur Corporation, P.O. Box 1165, Valdosta, GA 31603-1165, EPA Registration No. 6325-11.
2. Comply with the cite-all data provisions since your would need all sulfur data submitters' permission to use any relevant data on sulfur in support of your request if you indicate your source is not registered.

CONCURRENCES

SYMBOL ▶								
SURNAME ▶	<i>Handley</i>							
DATE ▶	<i>4/12/85</i>							

-2-

3. Also if you do not cite a registered source, you will also be subject to the data requirements imposed by the Sulfur Registration Standard.

Sincerely yours,

George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (TS-767)

RD/IRB:JOB:50448:LaRocca:RD-25:eg:Kendrick & Co:898-1270:3/8/85:Del.3/19/85
REVISED:JOB-85805:RD-85/10:EK:4/5/85:Del.4/12/85:

REG.# 36864-1 Chigg-Away

Pierson Laboratories, Inc.
P.O. Box 1097
Swansboro, N.C. 28584

- 1) [Note to PM: They have to specify which one they're using— I don't see a problem, unless they're using one of the cruder preparations. They say "USP", but I don't find such a designation in the brochure.]

Brinson Conerly
IRB/TSS
12/18/84

B Conerly

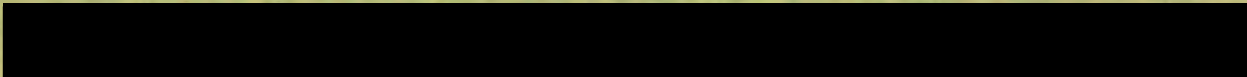
6 JUN 1984

Pierson Laboratories, Inc.
P.O. Box 1097
Swansboro, NC 28584

Attention: Thomas Behan

Gentlemen:

Subject: Chigg-Away
EPA Registration No. 36864-1



This apparently affects the presence or absence of other ingredients in your formulation as well. Please submit a corrected Confidential Statement of Formula in which a registered source of sulfur is cited. This new source may entail other ingredient revisions as well.

We would like your response within thirty (30) days.

Sincerely yours,

George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (TS-767)

REVISED:RD/IRB:DCR-04430:LaRocca:Raven:557-2226:pjb:RD-07:5/31/84:Del.6/15/84

CONCURRENCES							
SYMBOL ▶							
SURNAME ▶	<i>T. Behan</i>						
DATE ▶	<i>6/1/84</i>						

DRP

120857/01
4/17

17 MAY 1984

Mr. Thomas Behan
Pierson Laboratories, Inc.
P. O. Box 1097
Swansboro, NC 28584

Dear Mr. Behan:

Subject: Amendment-Label showing correct address
Chigg-Away
EPA Registration No. 36864-1
Your Application dated April 6, 1984

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records.

Sincerely yours,

George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (TS-767)

Enclosure

RD:IRB:DCR-05518:G.LaRocca:cml:RAVEN:557-2226:CBI-08A:5/3/84:Del.5/20/84

CONCURRENCES

SYMBOL ▶							
SURNAME ▶							
DATE ▶							

Pierson Laboratories, Inc.
EPA Registration Number: 36864-1

ACCEPTED
MAY 17 1984
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under
EPA Reg. No. 36864-1



CHIGG-AWAY

CAUTION: For External Use Only. Keep away from eyes or other mucous membranes. Not for prolonged use. If the condition for which this preparation is used persists or if a rash or irritation develops, discontinue use and consult physician. Not to be used on infants younger than two years.

WARNINGS: Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.

WORKS TWO WAYS

1. Effectively repels chiggers! Apply around feet, ankles, waist and to skin under all areas of tight fitting clothing and around all openings in outer clothing. Re-apply after swimming.

2. Effectively relieves itching and discomfort of all non-painful insect bites such as chiggers, mosquitoes, ticks, sand fleas and biting flies. Also relieves the itching of poison ivy and poison oak. The unique action of Chigg-away lotion soothes prompt relief to the source of irritation. Provides soothing relief from itching. Apply liberally and rub in well as needed.

DIRECTIONS: Do not reuse empty container. Wrap container and put in trash collection.

Manufactured For
PIERSON LABORATORIES, INC.
Bloomington, NC 28904
By L.T. Yen
Bloomington, MO 64608
© 1984 by L.T. Yen
All rights reserved

704180187



300-01

pierson laboratories, inc.

p.o. box 1097

swansboro, nc. 28584

919/326-3933
804/272-7313

April 6, 1984

Mr. George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (TS-767)
Environmental Protection Agency
1921 Jefferson Davis Highway
CM#2, Room 200
Arlington, VA 22202

Re: EPA Registration No. 36864-1

Dear George:

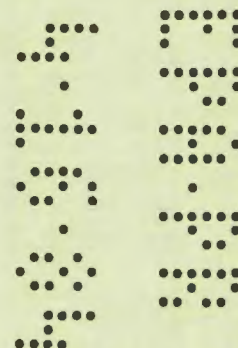
As I was reading your letter of March 21, 1984 with accompanying label approval, I noticed that apparently the old back panel of our label with our former address was inadvertently placed with the new front label for approval. We wish to correct the oversight and have enclosed the correct label with this letter.

We apologize for the error and ask that this label be approved and placed in our file. We respectfully ask that a copy of the approved label be sent to us. Thank you very much for helping us in this matter.

Sincerely,

Thomas E. Behan
Vice President

TEB/mlb
Enclosure



21 MAR 1984

Pierson Laboratories, Inc.
P.O. Box 1097
Swansboro, NC 28584

Attention: Tom Behan

Gentlemen:

Subject: Amendment - Formula Revision - Increase
Benzocaine Content Chigg-Away
EPA Registration No. 36864-1
Your Application Dated February 4, 1984

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records.

The revised formula is also acceptable and has been included in our files for the subject product.

At the next label printing revise the container disposal information to read.

Do not reuse bottle. Rinse thoroughly before discarding in trash.

Sincerely yours,

George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (TS-767)

Enclosure

DCR-05469:LaRocca:Raven:557-2226:CBI-21:KIM:2/29/84:Del.3/16/84

CONCURRENCES

SYMBOL ▶								
SURNAME ▶	J. B. Boshley							
DATE ▶	3/2/84							



CHIGG-AWAY

CAUTION: For External Use Only. Keep away from eyes or other mucous membranes. Not for prolonged use. If the condition for which this preparation is used persists or if a rash or eruption develops, discontinue use and consult physician. Not to be used on infants younger than two years.

WARNING: Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a poison control center immediately.

- WORKS TWO WAYS**
1. Effectively repels chiggers! Apply around feet, ankles, waist and to skin under all areas of tight fitting clothing and around all openings in outer clothing. Re-apply after swimming.
 2. Effectively relieves itching and discomfort of all non-painful insect bites such as chiggers, mosquitoes, bees, and bees and biting flies. The unique action of Chigg-Away lotion soothes itching relief from skin. Apply liberally and rub in well as needed.

DISPOSAL: Do not reuse empty container. Wrap container and put in trash collection.

Manufactured For
PERSON LABORATORIES, INC.
Cummings, NC 27029
By L.T. Van
Brockfield, MO 64608

EPA Reg. No. 25554-1
EPA Est. 05300-MO-01
Pat. Pend.



ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 21 1984

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.

3168104-1

U.P.C. # 76418-01897



pierson laboratories, inc.

p.o. box 1097

swansboro, nc. 28584

919/326-3933
804/272-7313

February 7, 1984

Mr. G. T. LaRocca
Product Manager (15)
Registration Div - (TS-767C)
EPA
1921 Jefferson Davis Highway
CM#2, Room 200
Arlington, VA 22202

Dear George:

Re: Reg. # 36864-1

Bob and I enjoyed visiting with you when we were in the area. As we discussed, enclosed you will find our EPA Form 8570-4, Confidential Statement of Formulation. In addition to the increase in benzocaine from 1% to 3%, we have made some minor adjustments in several other ingredients and totally eliminated two ingredients. The sole purpose of these adjustments, other than the increase in benzocaine, is to greatly improve the suspension of the product.

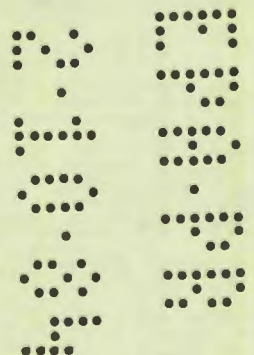
Also enclosed is a letter from Robert A. Eshelman of the FDA dated May 28, 1980. I talked with Mr. Eshelman in December, 1983 and he indicated to me that there had been no changes since May, 1980.

If you have any questions concerning this matter, please feel free to call.

Sincerely,

Tom Behan
Vice President

TB/mb
Enclosures (2)



Revised

12-5-83

received 12/12/83



CHIGG-AWAY

CAUTION: For External Use Only. Keep away from eyes or other mucous membranes. Not for prolonged use in the location for which the preparation is used. Periodic or a rash or unusual develops, discontinue use and consult physician. Not to be used on infants younger than two years.

WARNING: Keep this and all drugs out of the reach of children in case of accidental ingestion. Seek professional assistance or contact a poison center.

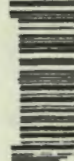
WORKS TWO WAYS

1. Effectively repels chiggers! Apply around feet, ankles, waist and to skin under armpits of legs during evening and around armpits in cooler clothing. Re-apply after swimming.
2. Effectively relieves itching and discomfort of an itchy rash. Apply to areas such as chiggers, insect bites, and hives and skin has and relieves the itching of mosquito and tick bites. The "chug action" of Chig-Away upon the skin is the source of relief.

DISPOSAL: Do not flush contents down sink or toilet. Wrap in plastic and dispose of properly.

Manufactured for: **HERSON LABORATORIES INC.**
Greenville, SC 29614

Net Wt. 2.0 oz (56.7 g)
Gross Wt. 2.1 oz (59.5 g)
Net Wt. 1.9 oz (53.5 g)
Net Wt. 1.8 oz (50.9 g)



UPC # 70418-01897



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

May 28, 1980

Mr. Thomas Behan
P.O. Box 147
Currituck, North Carolina 27929

Dear Mr. Behan:

This responds to your meeting of May 20, 1980 with Mr. Heller and myself concerning the status of your product "CHIGG-AWAY," offered for relief of itching from insect bites and for repelling chiggers. It is understood that the product we discussed will contain 10% sulfur and 1% benzocaine as the active ingredients.

Products similar to "CHIGG-AWAY" have been marketed over-the-counter for several years and are thus included in the OTC Drug Review. Pending a final monograph on products offered for the relief of itching caused by insect bites, marketing is done solely on your own responsibility.

The Food and Drug Administration instituted the OTC Drug Review to evaluate the safety and effectiveness of all OTC drugs on a class-by-class basis. The OTC Drug Review will categorize all OTC preparations in several basic categories. From the Review will be published monographs for each basic category to establish conditions under which OTC drugs will be generally recognized as safe and effective and not misbranded. Each OTC product will have to either meet the standards of an appropriate monograph which may require reformulation and/or relabeling, or seek approval through the new drug procedures of the Act.

In response to your inquiry, we would not object at this time if you deleted the phrase "*** because of risk of methemoglobinemia." from the warning section. However, we do expect you to retain the warning "*** Not to be used on infants younger than two years." The OTC Drug Review Panel reviewing topical analgesics drug products concluded in its report to the Agency that a specific warning regarding the risk of methemoglobinemia was not necessary for topical benzocaine preparations (up to 20% benzocaine). The Panel did conclude however, that such preparations should not be used on children under two except under a physician's supervision.

Drug producers are required to manufacture drugs in compliance with Current Good Manufacturing Practice (CGMP) for drugs and the Fair Packaging and Labeling Act (FPLA) regulations. The CGMP regulations for drugs are found in Title 21 Code of Federal Regulations, Part 210 and 211. The FPLA regulations for drugs are contained in 21 CFR 201. Additional pertinent regulations, including required warnings, for drugs are found in 21 CFR volumes containing Parts 200-299 and 300-499. These two (2) volumes may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C., 20402, at a cost of \$4.00 and \$7.00 respectively.

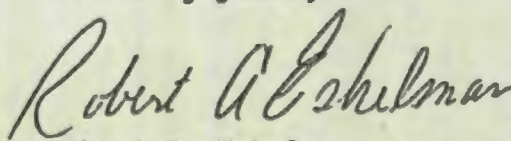
Drug producers as defined in Section 510(a)(1) of the Federal Food, Drug, and Cosmetic Act are required to register with the Food and Drug Administration and submit a list of all drugs produced. We are enclosing forms and instructions for registering and listing. Such registration and listing do not, in any way, connote approval by the Food and Drug Administration.

As you know, your product is also subject to the jurisdiction of the Environmental Protection Agency (EPA) since it bears claims for repelling insects. The fact that we do not object to the marketing of your product on your own responsibility pending completion of the OTC Drug Review does not, in anyway, exempt you from fully complying with the requirements of EPA.

We are enclosing a copy of the Federal Food, Drug, and Cosmetic Act and a booklet that summarizes the requirements of the Act.

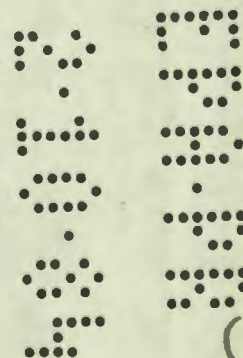
We hope this information is helpful.

Sincerely yours,



Robert A. Eshelman
Assistant to the Director
Division of Drug Labeling Compliance
Bureau of Drugs

Enclosures:
Drug Registration/Listing Forms
FD & C Act
Pub. No. 79-1042



APR 15 1981

Pierson Laboratories, Inc.

P.O. Box 147

Currituck, NC 27929

Attention: Tom Behan

Gentlemen:

Subject: Amendment-Increase benzocaine to 1%

Chigg-Away

EPA Registration No. 36864-1

Application dates of November 28, 1980; February 23 and March 9, 1981

The amendment referred to above, submitted in connection with registration under Section 3(c)(7)(B) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA), is acceptable.

A stamped copy of the label is enclosed for your records.

The following revisions should be made at the next label printing:

1. Delete "General Classification" after "Directions for Use" since products with these active ingredients have not yet been classified.
2. Add the following to the Hazards to Humans text.

If in eyes, flush with plenty of water. Get medical attention if irritation persists.

Please note that future submissions of the confidential statement of formula should list the amount of [REDACTED] so that the ingredients total in the product will be 100% instead of 100.5% due to the uncompensated for increase of 0.5% Benzocaine in the calculation.

Sincerely,

BEST DOCUMENT AVAILABLE

George T. LaRocca

Product Manager (15)

Insecticide-Rodenticide Branch

Registration Division (TS-767)

Enclosure

OPTS:LARocca:34516:2668A-DPT-WANG:RAVEN:479-2018:3/20/81

ROUTING AND TRANSMITTAL SLIP		ACTION
1 TO (Name, office symbol or location)	INITIALS	CIRCULATE
	DATE	COORDINATION
2	INITIALS	FILE
	DATE	INFORMATION
3	INITIALS	NOTE AND RETURN
	DATE	PER CONVERSATION
4	INITIALS	SEE ME
	DATE	SIGNATURE

REMARKS

Phone call memo to Carl Schreck is attached. Please call the registrant and tell him to send copies of the background materials referenced in the Military Surgeon article and others if possible. This should give us enough to go on.

Do NOT use this form as a RECORD of approvals, concurrences, disapprovals, clearances, and similar actions

FROM (Name, office symbol or location)

DATE

PHONE

Phil Hutton

8/5/77

55325

OPTIONAL FORM 41
AUGUST 1967
GSA FPMR (41CFR) 101-11.6

648-10-61504-1 552-103

5041 101

BEST DOCUMENT AVAILABLE

106



2
pierson laboratories, inc.

p. o. box 147

currituck, nc 27929

919/232-2116

March 9, 1981

Mr. Dana R. Pilitt
Registration Division (TS-767)
Product Manager #15
Environmental Protection Agency
Crystal Mall #2
401 M Street, S.W.
Washington, D.C. 20460

Dear Mr. Pilitt:

Enclosed is our proposed new label art work. Our registration number is 36864-1.

Thank you very much for the information you sent to me on Lindane.

Sincerely,

Tom Behan
Vice President
Marketing

TB/mb
Enclosures (5)

70-27-2

84-843

206

3

ACCEPTED
 APR 10 1981
 Under the Federal Insecticide,
 Fungicide, and Rodenticide Act,
 as amended, for the pesticide
 registered under
 EPA Reg. No. 36841

RELIEF FROM CHIGGERS

CHIGG AWAY

TWO WAY ACTION

1. REPELS CHIGGERS
2. RELIEVES ITCHING

ACTIVE INGREDIENTS

Precipitated Sulfur	10.0%
Benzocaine	1.0%
Inert Ingredients	89.0%

KEEP OUT OF REACH OF CHILDREN
CAUTION SEE BACK PANEL FOR
 ADDITIONAL PRECAUTIONS

4 fluid ounces

CHIGG-AWAY
 For External Use Only—Do Not Take Internally

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS

Keep away from eyes or other mucous membranes. Not for prolonged use. If the condition for which this preparation is used persists or if a rash or irritation develops, discontinue use and consult physician. Not to be used on infants younger than two years.

Directions For Use General Classification
 It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

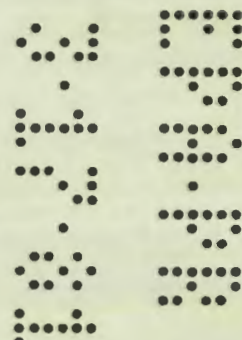
WORKS TWO WAYS

1. Effectively repels chiggers! Apply around feet, ankles, waist and to skin under all areas of tight fitting clothing and around all openings in outer clothing. Re-apply after swimming.
2. Effectively relieves itching and discomfort of all nonpoisonous insect bites, such as chiggers, mosquitoes, ticks, sand fleas and biting flies, and also relieves itching of poison ivy and poison oak. The unique action of Chigg-Away lotion carries prompt relief to the source of irritation. Apply topically and rub in well as needed.

DISPOSAL
 Do not reuse empty container. Wrap container and put in trash collection.

MANUFACTURED FOR:
 Parson Laboratories, Inc.
 P. O. Box 147
 Camluc, N. C. 27929

NDC No. 45681-04
EPA Reg. No. 36864-1
EPA Est. 41502-MO-1
Pat. Pend.



Memorandum

Date: March 13, 1981

Subject: EPA Reg. No. 36864-1 CHIGG-AWAY
Caswell #812, 80

From: B. T. Backus
IRB/TSS

To: Mr. George LaRocca
Product Manager 15

Registrant: Pierson Laboratories, Inc.
c/o James Bendure
2304 W. 105
Leawood, KS 66206

Active Ingredients (label declaration):

Precipitated Sulfur.....	10.0%
Benzocaine.....	1.0%
Confidential Formulation:.....	89.0%

Background:

The company is changing the amount of benzocaine in its formulation from 0.5 to 1.0%, and is also seeking to revise its label statement regarding risk of methemoglobinemia in children of under two years of age. The statement: "Not to be used on infants younger than two years." would be retained.

According to the 4th edition of Clinical Toxicology of Commercial Products, benzocaine, despite its low water solubility and poor absorption from most sites, has elicited severe methemoglobinemia on occasion in both children and adults. Such reactions have followed topical application of ointments containing benzocaine. In some cases systemic absorption may have been enhanced by inflamed skin. The methemoglobinemia responds dramatically to methylene blue, so the condition is treatable.

The registrant has submitted a copy of a letter dated May 28, 1980 from the Food and Drug Administration in which it is stated that no objection would be raised to deleting the phrase "because of risk of methemoglobinemia" from the label. The letter also notes that an OTC Drug Review Panel reviewing topical analgesics concluded in a report to FDA that a specific warning regarding the risk of methemoglobinemia was not necessary for topical benzocaine preparations containing up to 20% benzocaine.

207

5

Comments and Recommendations:

1. The pest-mitigating active ingredient in this formulation is the sulfur which serves as a chigger repellent. The function of the benzocaine is to relieve itching.
2. FDA has indicated that no mention of methemoglobinemia hazard potential is necessary for a topical analgesic containing less than 20% benzocaine. Also, there are many topical analgesic products (not necessarily pesticides) containing 1% or more benzocaine which do not have this statement.
3. IRB/TSS would have no objection, on the basis of hazard to humans or domestic animals, to the increase of benzocaine in this formulation from 0.5 to 1.0% and to deletion of the phrase: "...because of risk of methemoglobinemia."

Labeling:

1. The "General Classification" can be deleted.
2. It would be preferable to have a Precautionary Label Statement for this product regarding eye exposure, something like: "If in eye, flush with plenty of water. Get medical attention if irritation persists."

Byron T. Backus 03/13/51

Byron T. Backus
IRB/TSS

208

REVIEW COMMENTS SHEET		1. Application Date	2. Registration No. 6
3. Response Code		4. Date Received	5. Telephone No.
6. Applicant Name & Address Pierson Laboratories, Inc. 2304 W. 105 Leawood, KS 66206			7. Originator
8. Product Name Chigg-away			
COMMENTS			
1) Ingredients total 100.5% as stated. If the rest of the ingredients are the same and amount of [REDACTED] changed to [REDACTED] %'s will be 100%.			
Formulation otherwise ok.			
2) Registrant has already agreed to change "confidential formulation" to "inert ingred's". Label otherwise ok by chemistry.			
Pierson Corp RB/TSS 3/5/81			



7
pierson laboratories, inc.

p. o. box 147

currituck, nc 27929

919/232-2116

February 23, 1981

Dr. Dana R. Pilitt
Registration Division
Environmental Protection Agency
Office of Pesticide Programs
Registrar Division
HM 547
401 "M" Street, S.W.
Washington, D.C. 20460

Dear Dr. Pilitt:

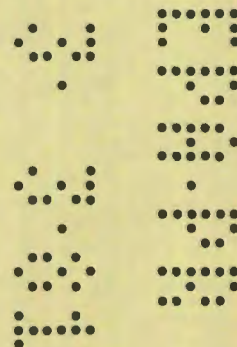
Enclosed is our Confidential Statement of Formula reflecting the desired changes of our November 28, 1980 submission. You indicated you would be willing to help fill out the form and you will find all the necessary information in our file at the EPA. Our Chigg-Away registration number is EPA Reg. No. 36864-1. We will delete the phrase "confidential formulation" and go with Inert Ingredients 89.0%.

Thanks for all your help.

Sincerely,

Tom Behan
Vice President
Marketing

TB/mb
Enclosure



C.

Certification Letter

Name of Company: Pierson Laboratories, Inc.

Name of Product: Chigg-Away

EPA Reg. No. or File Symbol: 36864-1

I certify that the following active ingredient(s) will be present in this product solely as the result of the use by applicant of one or more other technical-grade or manufacturing-use products registered under FIFRA and purchased by applicant from another producer(s):

SULFUR

I further certify that applicant does not own and is not owned or controlled by any of the other producer companies from whom the applicant will purchase these active ingredient(s), and that the applicant is not owned or controlled by any other company that also owns or controls any of those producer companies.

Signature Thomas E. Bohan

Date Signed April 3, 1981

Title Vice President

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MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Jay Ellenberger, Environmental
Protection Agency

DATE: June 5, 1980

FROM : Robert Eshelman, OTC Compliance Branch
HFD-312

SUBJECT: "CHIGG-AWAY" - Insect Repellent

Attached is a copy of a letter sent to Mr. Behan, Currituch, North Carolina concerning his product "CHIGG-AWAY" which is offered for the relief of itching due to insect bites and also as a repellent for chiggers. The product is manufactured for Pierson Laboratories, Inc., Leawood, Kansas. EPA Registration number is listed as 36864-1 and the EPA Establishment number is 41502-MO-1.

In 1975 we reviewed the product and advised your office that we felt the warning regarding the risk of methemoglobinemia should be on the label. Subsequently, FDA has published a proposed regulation covering OTC topical analgesics including benzocaine. The report extensively covers the risk of methemoglobinemia from topical use of benzocaine. The panel concluded that there is not sufficient evidence available to warrant inclusion of a warning regarding methemoglobinemia. Therefore requiring such a warning would not be enforceable on our part.

If you have any questions, please call me.

Bob

Robert A. Eshelman

Attachment:
copy of 5/28/80 letter to Mr. Behan



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

May 28, 1980

Mr. Thomas Behan
P.O. Box 147
Currituck, North Carolina 27929

Dear Mr. Behan:

This responds to your meeting of May 20, 1980 with Mr. Heller and myself concerning the status of your product "CHIGG-AWAY," offered for relief of itching from insect bites and for repelling chiggers. It is understood that the product we discussed will contain 10% sulfur and 1% benzocaine as the active ingredients.

Products similar to "CHIGG-AWAY" have been marketed over-the-counter for several years and are thus included in the OTC Drug Review. Pending a final monograph on products offered for the relief of itching caused by insect bites, marketing is done solely on your own responsibility.

The Food and Drug Administration instituted the OTC Drug Review to evaluate the safety and effectiveness of all OTC drugs on a class-by-class basis. The OTC Drug Review will categorize all OTC preparations in several basic categories. From the Review will be published monographs for each basic category to establish conditions under which OTC drugs will be generally recognized as safe and effective and not misbranded. Each OTC product will have to either meet the standards of an appropriate monograph which may require reformulation and/or relabeling, or seek approval through the new drug procedures of the Act.

In response to your inquiry, we would not object at this time if you deleted the phrase "*** because of risk of methemoglobinemia." from the warning section. However, we do expect you to retain the warning "*** Not to be used on infants younger than two years." The OTC Drug Review Panel reviewing topical analgesics drug products concluded in its report to the Agency that a specific warning regarding the risk of methemoglobinemia was not necessary for topical benzocaine preparations (up to 20% benzocaine). The Panel did conclude however, that such preparations should not be used on children under two except under a physician's supervision.

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Drug producers are required to manufacture drugs in compliance with Current Good Manufacturing Practice (CGMP) for drugs and the Fair Packaging and Labeling Act (FPLA) regulations. The CGMP regulations for drugs are found in Title 21 Code of Federal Regulations, Part 210 and 211. The FPLA regulations for drugs are contained in 21 CFR 201. Additional pertinent regulations, including required warnings, for drugs are found in 21 CFR volumes containing Parts 200-299 and 300-499. These two (2) volumes may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C., 20402, at a cost of \$4.00 and \$7.00 respectively.

Drug producers as defined in Section 510(a)(1) of the Federal Food, Drug, and Cosmetic Act are required to register with the Food and Drug Administration and submit a list of all drugs produced. We are enclosing forms and instructions for registering and listing. Such registration and listing do not, in any way, connote approval by the Food and Drug Administration.

As you know, your product is also subject to the jurisdiction of the Environmental Protection Agency (EPA) since it bears claims for repelling insects. The fact that we do not object to the marketing of your product on your own responsibility pending completion of the OTC Drug Review does not, in anyway, exempt you from fully complying with the requirements of EPA.

We are enclosing a copy of the Federal Food, Drug, and Cosmetic Act and a booklet that summarizes the requirements of the Act.

We hope this information is helpful.

Sincerely yours,

Robert A. Eshelman

Robert A. Eshelman
Assistant to the Director
Division of Drug Labeling Compliance
Bureau of Drugs

Enclosures:
Drug Registration/Listing Forms
FD & C Act
Pub. No. 79-1042

253

148



pierson laboratories, inc.

p. o. box 147

currituck, nc 27929

919/232-2116

36864 -

~~36876-1~~

November 28, 1980

Mr. Jay Ellenberger
Environmental Protection Agency
Office of Pesticide Programs
Registrar Division
HM 547
401 "M" Street, S.W.
Washington, D.C. 20460

Dear Jay:

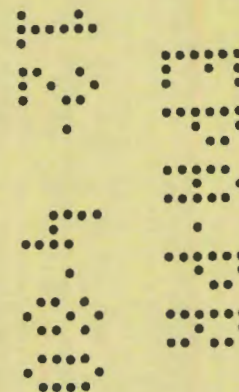
Enclosed are five (5) copies of the proposed new label changes. I had a meeting with Mr. Robert S. Eshelman of the Food and Drug regarding increasing the amount of benzocaine from 0.5% to 1.0% and also deleting the phrase "because of risk of methemoglobinemia." Enclosed are his comments. Also enclosed is a letter from John Doull that we would like placed in our file.

Sincerely,

Tom Behan

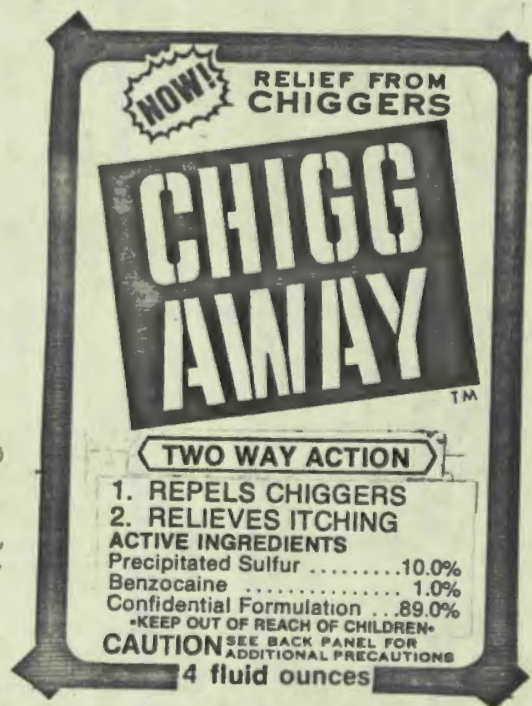
Tom Behan
Vice President
Marketing

TB/mb
Enclosures



13

603



10

8

10

TWO WAY ACTION

9

CAUTION

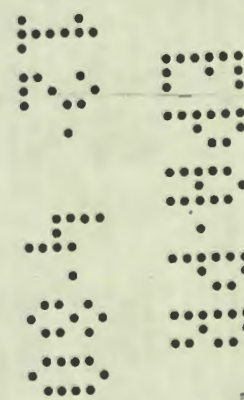
SEE BACK PANEL FOR ADDITIONAL PRECAUTIONS

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9

9

TWO WAY ACTION



202

14

CHIGG-AWAY

For External Use Only—Do Not Take Internally

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

Keep away from eyes or other mucous membranes. Not for prolonged use. If the condition for which this preparation is used persists or if a rash or irritation develops, discontinue use and consult physician. Not to be used on infants younger than two years.

Directions For Use General Classification

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

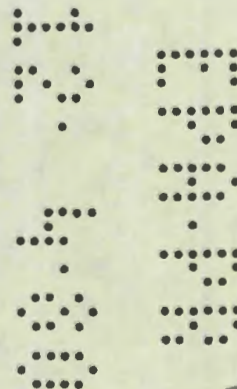
WORKS TWO WAYS

1. **Effectively repels chiggers!** Apply around feet, ankles, waist and to skin under all areas of tight fitting clothing and around all openings in outer clothing. Re-apply after swimming.
2. **Effectively relieves itching** and discomfort of all non-poisonous insect bites such as chiggers, mosquitoes, ticks, sand fleas and biting flies. The unique action of Chigg-Away lotion carries prompt relief to the source of irritation. Provides soothing relief from itching. Apply topically and rub in well as needed.

DISPOSAL

Do not reuse empty container. Wrap container and put in trash collection.

MANUFACTURED FOR: NDC No. 45591-04
Person Laboratories, Inc. EPA Reg. No. 38864-1
P.O. Box 147 EPA Est. 41502-MO-1
Carruck, N.C. 27929 Pat. Pend.



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RECORD OF COMMUNICATION

☒ PHONE CALL ☐ DISCUSSION ☐ FIELD TRIP ☐ CONFERENCE
☐ OTHER (SPECIFY)

(Record of item checked above)

TO: Jay Ellenberger
PM Team 15

FROM: Tom Behan
Piersen Labs. Inc.

DATE: 5/8/80 - 5/15/80
TIME: —

SUBJECT

CHIGG-AWAY/EPA Reg. No. 36864-1 : Request to delete precaution

SUMMARY OF COMMUNICATION

Behan is interested in deleting "because of risk of methemoglobinemia." from the restriction "Not to be used in infants younger than two years ...". He thinks it is not required by FDA and besides it is hurting their marketing potential.

I told Behan I'd check with FDA/BD on this request. I talked with Bob Heller of FDA who said the registrant would have to file the request to FDA with information supporting the request.

The origin of the restriction is FDA's review, dated 10/29/75, which states this restriction is suggested by the OTC Drug panel reviewing benzocaine.

Also, Behan requested if the label could be amended to include the claim "Confidential Formula" on the label and in the general text. I said yes.

CONCLUSIONS, ACTION TAKEN OR REQUIRED

I called back Behan and told him he had 3 options: 1) forget the request, 2) submit a formal request to FDA to remove the portion of the restriction, and 3) ~~the~~ drop benzocaine from the formulation, thereby removing the necessity for the statement. (Behan believes benzocaine is not really needed in product since it's only acting as an analgesic.)

Behan will think about these options before any further action.

INFORMATION COPIES

TO:

BEST DOCUMENT AVAILABLE

194

19

APR 16 1980

Pierson Laboratories, Inc.
2304 West 105 Street
Leawood, KA 66206

Attention: James Bendure

Dear Mr. Bendure:

Subject: SUBMISSION: SHELF LIFE STABILITY
CHIGG-AWAY
EPA Registration No. 36864-1
Application Date of December 14, 1979

This is to acknowledge receipt of the shelf life stability study on Chigg-Away, EPA Registration No. 36864-1. The data has been reviewed and found acceptable and will be added to the product registration file.

Sincerely,

George T. LaRocca
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (TS-767)

TS767:GTLarocca:xfr310:jcb:DCR#14324:RAVEN:479-2018:02/01/80

192



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

May 28, 1980

Mr. Thomas Behan
P.O. Box 147
Currituck, North Carolina 27929

Dear Mr. Behan:

This responds to your meeting of May 20, 1980 with Mr. Heller and myself concerning the status of your product "CHIGG-AWAY," offered for relief of itching from insect bites and for repelling chiggers. It is understood that the product we discussed will contain 10% sulfur and 1% benzocaine as the active ingredients.

Products similar to "CHIGG-AWAY" have been marketed over-the-counter for several years and are thus included in the OTC Drug Review. Pending a final monograph on products offered for the relief of itching caused by insect bites, marketing is done solely on your own responsibility.

The Food and Drug Administration instituted the OTC Drug Review to evaluate the safety and effectiveness of all OTC drugs on a class-by-class basis. The OTC Drug Review will categorize all OTC preparations in several basic categories. From the Review will be published monographs for each basic category to establish conditions under which OTC drugs will be generally recognized as safe and effective and not misbranded. Each OTC product will have to either meet the standards of an appropriate monograph which may require reformulation and/or relabeling, or seek approval through the new drug procedures of the Act.

In response to your inquiry, we would not object at this time if you deleted the phrase "*** because of risk of methemoglobinemia." from the warning section. However, we do expect you to retain the warning "*** Not to be used on infants younger than two years." The OTC Drug Review Panel reviewing topical analgesics drug products concluded in its report to the Agency that a specific warning regarding the risk of methemoglobinemia was not necessary for topical benzocaine preparations (up to 20% benzocaine). The Panel did conclude however, that such preparations should not be used on children under two except under a physician's supervision.

BEST DOCUMENT AVAILABLE

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Drug producers are required to manufacture drugs in compliance with Current Good Manufacturing Practice (CGMP) for drugs and the Fair Packaging and Labeling Act (FPLA) regulations. The CGMP regulations for drugs are found in Title 21 Code of Federal Regulations, Part 210 and 211. The FPLA regulations for drugs are contained in 21 CFR 201. Additional pertinent regulations, including required warnings, for drugs are found in 21 CFR volumes containing Parts 200-299 and 300-499. These two (2) volumes may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C., 20402, at a cost of \$4.00 and \$7.00 respectively.

Drug producers as defined in Section 510(a)(1) of the Federal Food, Drug, and Cosmetic Act are required to register with the Food and Drug Administration and submit a list of all drugs produced. We are enclosing forms and instructions for registering and listing. Such registration and listing do not, in any way, connote approval by the Food and Drug Administration.

As you know, your product is also subject to the jurisdiction of the Environmental Protection Agency (EPA) since it bears claims for repelling insects. The fact that we do not object to the marketing of your product on your own responsibility pending completion of the OTC Drug Review does not, in anyway, exempt you from fully complying with the requirements of EPA.

We are enclosing a copy of the Federal Food, Drug, and Cosmetic Act and a booklet that summarizes the requirements of the Act.

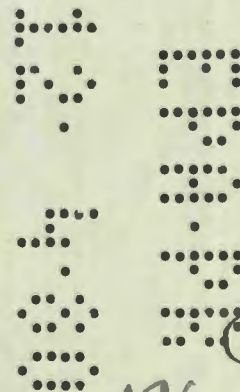
We hope this information is helpful.

Sincerely yours,

Robert A. Eshelman

Robert A. Eshelman
Assistant to the Director
Division of Drug Labeling Compliance
Bureau of Drugs

Enclosures:
Drug Registration/Listing Forms
FD &C Act
Pub. No. 79-1042



196



THE UNIVERSITY OF KANSAS MEDICAL CENTER
COLLEGE OF HEALTH SCIENCES AND HOSPITAL

RAINBOW BOULEVARD AT 39TH • KANSAS CITY, KANSAS 66103

SCHOOL OF MEDICINE
SCHOOL OF NURSING
SCHOOL OF ALLIED HEALTH
UNIVERSITY HOSPITAL

October 21, 1980

DEPARTMENT OF PHARMACOLOGY
(913) 588-7140.

Mr. Jim Bendure
2304 W. 105th Street
Leawood, Kansas 66206

Dear Mr. Bendure:

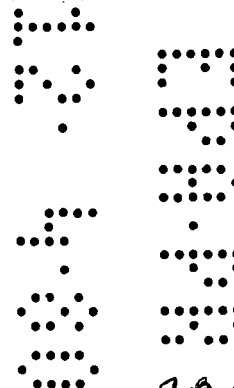
With regard to your questions about the acute hazard or poison control recommendations for your product, CHIGG-AWAY, we have reviewed the acute toxicity data of the product and of the individual ingredients in the product. All of the ingredients (sulfur, [REDACTED]) except benzocaine are virtually nontoxic acutely (LD₅₀ values in excess of 1 gram/kg orally). Benzocaine is considered to be a local anesthetic of low toxicity and at the concentration used in your product would be considered to have little or no toxic significance. The acute toxicity studies carried out on the formulated product confirm the low toxicity of CHIGG-AWAY and demonstrate an excellent margin of safety in the poison control area. We were unable to produce mortality in rats with acute oral doses of the formulation in excess of 4 grams/kilogram (Ref: Acute oral toxicity of CHIGG-AWAY and its ingredients in adult male rats, Progress Report submitted March 20, 1977). This dosage level would be equivalent to a dose of 280 grams in a 70 kilogram adult or 40 grams in a 10 kilo child.

Using the general poison control classification criteria, this would place your product in the practically nontoxic category.

Sincerely yours,

John Doull, M.D., Ph.D.
Professor of Pharmacology and Toxicology

JD/mkh



200

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

1. File Symbol/Reg. No. 3864-1 2. RM 15 3. Action Code 550 ^{9/1/80} ¹⁹²⁶⁰ ² ⁵⁷⁰ ^W

4. Child resistant packaging. 5. ☐ Registration ☒ Amendment

☐ Yes- Has complied with regulation. ☐ Conditional ☒ Unconditional

6. Proposed classification. 7. Final classification

☐ Restricted ☐ Restricted ☐ Not classified
☐ General ☐ General

8. Date on application

9. Date received by RM

1 2 1 4 7 9
MO DAY YR

1 2 2 1 7 9
MO DAY YR

10. *Product type(circle one): A AR B/F D OE OF F H I IR PGR R S

11. *Priority(circle one): 1 2 3 4 5 6 7

12. *Applicant

13. *Chemical name

14. *Chemical code

15. Proposed use Self-life Stability - Data

16. Method of support

17. Certification statement submitted

☐ Cite-all ☐ Combined ☐ Yes ☒ Not applicable
☐ Alternate ☒ Not applicable ☐ No ☐ Not submitted
☐ Not submitted

18. Petitions pending

19. Sent to Federal Register Section for publication

Notice of Receipt

Notice of Registration

MO DAY YR

MO DAY YR

20. Reviews requested

	DATE SENT	DUE DATE	DATE RETURNED	RESPONSE CODE	RESPONSE DATE
HED					
SPS					
RCS					
EEB					
TB					
RD					
RM					
TSS					
Precaut. Labeling					
Chemistry	<u>1/11/79</u>				
Stability					

35 1-22-80 DRP

NAC 1-11-80

21. Status

22. FINAL ACTION: Response code

Response date

35

APR 16

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12/14/79
36864-~~2~~1

21

Dear Jim,

Enclosed is shelf-life stability study on Chigg-Away. Jim Bendure's address is the same, but mine has changed to P. O. Box 147, Cubrituck, N.C. 27929.

Hope you and your family have a very Merry Christmas.

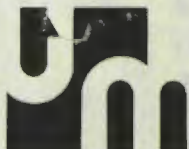
Sincerely,
Tom

BEST DOCUMENT AVAILABLE

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UNIVERSITY OF MISSOURI - KANSAS CITY

22
School of Pharmacy

The Bio-Analytics Laboratory

Room M3-102 — School of Medicine
2411 Holmes Street
Kansas City, Missouri 64108
Telephone: (816) 421-5598

November 2, 1979

Shelf-life stability study on Chigg-Away EPA file symbol 36864-R for Pierson Laboratories, Inc.

Received for analysis on 10/18/79 sample identified as manufactured on 8/15/78 and stored at room temperature since manufacture. The following assays were conducted for sulfur and benzocaine and the results tabulated.

Sulfur - Assayed on Varian 1200 atomic absorption spectrophotometer using 1:10⁵ dilution with heptane.

Seven samples were assayed:

1. 9.97g/100ml
2. 9.98g/100ml
3. 9.95g/100ml
4. 9.96g/100ml
5. 9.98g/100ml
6. 9.97g/100ml
7. 9.97g/100ml

mean = 9.969 ± .011

Benzocaine - Assayed on Varian 3500 GLC/CDS III with 10% OV-101 column and flame ionization detection.

Seven samples were assayed:

1. 5.11mg/ml
2. 5.09mg/ml
3. 5.11mg/ml
4. 5.10mg/ml
5. 5.10mg/ml
6. 5.11mg/ml
7. 5.10mg/ml

mean = 5.103 ± .007

Phil E. Psaltis

Phil E. Psaltis

Ph.D. Candidate

School of Pharmacy



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

23

10 JAN 1978

Pierson Laboratories, Inc.
P.O. Box 6503
Leawood, Kansas 66206

Gentlemen:

Subject: Chigg-Away
EPA File Symbol 36864-R
Your application of November 26, 1977

The product referred to above will be acceptable for registration under the Federal Insecticide, Fungicide, and Rodenticide Act; provided, finished labeling is submitted incorporating the following revisions.

"EPA Reg. No. 36864-1" is being reserved for this product. This appear on the finished label. The "Notice of Registration" will be issued when five (5) copies of the acceptable finished (printed) labeling are submitted. Finished labeling is that which will be attached to or accompany the product. Refer to the attached A-79 Enclosure.

To expedite handling, please return the enclosed duplicate copy of this letter with your finished labeling.

This letter does not constitute registration, and the product may not be lawfully marketed in interstate commerce until it is registered.

The submitted accelerated storage stability data is acceptable on an interim basis pending the results of the full 12 month study. The results of the 12 month study must be received by EPA within 2 years after the granting of registration.

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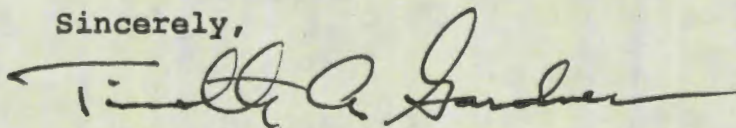
84843

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I have enclosed a sheet on type size requirements for your
convenience.

Sincerely,



Timothy A. Gardner
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (WH-567)

62.12.27

84.843

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September 7, 1977

Mr. Douglas D. Campt
Acting Director
Registration Division (WH-567)
United States Environmental Protection Agency

Dear Mr. Campt:

We are requesting a (75) day extension on our application in order to complete the efficacy study.



A handwritten signature in blue ink that reads "Tom Behan".

Tom Behan
Pierson Laboratories, Inc.

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26

REPORT OF TELEPHONE CALL OR VISITOR			NOTE: Complete this form. Write "NA" where not applicable.
<input checked="" type="checkbox"/> INCOMING CALL		VISITOR	DATE 4/18 and 4/19/78
<input checked="" type="checkbox"/> OUTGOING CALL		CONGRESSIONAL	TIME OF CALL 3:45 pm 9:30 am
NAME AND ADDRESS OF CALLER OR VISITOR Tom Behen and Jim Bendure Pierson Labs, Inc. Lenwood, KS			PHONE NO. (Include Area Code or IDS No.) (816) 753-4600 x 276
			REGISTRATION, ID NO. OR FILE SYMBOL 36864-1
			DATE OF LATEST SUBMISSION
BRIEF SUMMARY OF CONVERSATION Behen called 3:45 pm - 4/18/78 to request that he be given a copy of all data submitted for this product. The reason being that apparently the co. had given us only copy, and he needed a copy by 4/19 to show to Col. DuBois of US Army Pest Control Board - and Miller-Morton Co.			
ACTION TAKEN OR RECOMMENDED I called Jim Bendure at 9:30 am 4/19/78, since he has signed all co. correspondence & applic. forms for his own acknowledgment of this request; he did so acknowledge. I xeroxed Access. #'s 230522, 230523, and 230524, as well as the Ltr. of 4/2/76 from Univ. Kansas med. Center, and all other reprints received 9/8/77. I handed these copies to Tom Behen at 10:40 am 4/19/78.			
BEST DOCUMENT AVAILABLE			
RECORDED BY (Name) J88/lenburger		REFERRED TO (Name)	

189

139

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDES PROGRAMS
REGISTRATION DIVISION (WH-567)
WASHINGTON, D.C. 20460

EPA REGISTRATION NO.

36864-1

DATE OF ISSUANCE

March 1, 1978 28

TERM OF ISSUANCE

Registration

NAME OF PESTICIDE PRODUCT

CHUG- AWAY

NOTICE OF PESTICIDE:



REGISTRATION



REREGISTRATION

(Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended)

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

Pierson Laboratories, Inc.
c/o James Benware
2304 West 105 Street
Lawson, Kansas 66206

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

At the next label printing, the heading "ACTIVE INGREDIENT" should be moved to the left to be in line with the ingredients.

Send us three original copies of the label for our files.

Note that this submission was processed and accepted under the 1947 Federal Insecticide, Fungicide and Rodenticide Act. At such time as re-registration is required or amendments are proposed, the Registration, Re-registration and Classification Procedures, as published in the Federal Register on July 3, 1975, will be applied. Refer to Section 162.23 of that document. Refer also to FR Notice 75-1 and 75-4.

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ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL

DATE

1 88

ACCEPTED
36864-1
MAR 14 1978
UNDER FEDERAL INSECTICIDE
FUNGICIDE AND RODENTICIDE ACT
FOR ECONOMIC POISON REGISTER-
ED UNDER NO. 36864-1 SUBJECT
TO ATTACHED COMMENTS.

NOW!

**RELIEF FROM
CHIGGERS**

**CHIGG
AWAY**

TWO-WAY ACTION

REPELS CHIGGERS | **RELIEVES ITCHING OF CHIGGER BITES**

ACTIVE INGREDIENTS
Precipitated Sulfur 10.0%
Benzocaine 0.5%

INERT INGREDIENTS 69.5%

KEEP OUT OF REACH OF CHILDREN

CAUTION SEE BACK PANEL FOR
ADDITIONAL PRECAUTIONS
4 fluid ounces

CHIGG-AWAY

For External Use Only — Do Not Take Internally

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

Keep away from eyes or other mucous membranes. Not for prolonged use. If the condition for which this preparation is used persists or if a rash or irritation develops, discontinue use and consult physician.

Not to be used on infants younger than two years because of risk of methemoglobinemia.

Directions For Use General Classification

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

WORKS TWO WAYS

1. Effectively repels chiggers! Apply around ankles, waist and to skin under all areas of tight fitting clothing and around all openings in outer clothing. Re-apply after heavy exercise or swimming.
2. Relieves itching and discomfort of bites from chiggers, mosquitoes, ticks and biting flies. The unique action of Chigg-Away lotion carries prompt relief to the source of irritation. Provides soothing relief from itching. Apply topically and rub in well as needed.

DISPOSAL

Do not reuse empty container. Wrap container and put in trash collection.

Pierson Laboratories, Inc.
P.O. Box 6503
Leawood, Ks. 66206

EPA Reg. No. 36864-1
EPA Est. No.

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• SAME 578 •

36864-1 141

inst

36864-R

1-23-78

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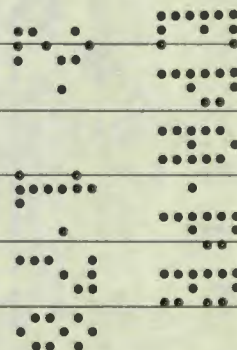
Mrs. Ellenberger-

Here is the label copy for our product. This is the actual size label that will be used on the 4 oz container. I will appreciate you giving me a call regarding the approval for use.

Sincerely,

Jim Berhane

BEST DOCUMENT AVAILABLE



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SUBMISSION REVIEW RECORD				1. REGISTRATION NUMBER				CYCLE	2. DATE RECEIVED		
3. 3CID PUBLICATION NECESSARY				4. PETITION NO.					MO	DAY	YR
6. METHOD OF SUPPORT				7. PRODUCT MANAGER				NO.	8. PROJECTED RETURN		
9. DATE PULLED		10. DATE PUBLISHED		11. ACTION TYPE				CODE	12. OUTGOING DATE		
REV. SEC.	REVIEW TYPE CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER				COM-MENT CODE	DATE REVIEW COMPLETED		
									MO	DAY	YR
	A	REVIEWABILITY TEAM									
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW									
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW									
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW									
	E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW	182					NAC	0	2	08 7 8
	F	PRODUCT MANAGER									
	G	INTERAGENCY REFERRAL									
	H	COST-BENEFIT REVIEW									
	I	PUBLIC COMMENTS REVIEW									
	J	EEE BRANCH INSECTICIDE EFFICACY									
	K	EEE BRANCH HERBICIDE EFFICACY									
	L	EEE BRANCH FUNGICIDE EFFICACY									
	M	EEE BRANCH RODENTICIDE EFFICACY									
	N	EEE BRANCH DISINFECTANT EFFICACY									
	O	CHEMISTRY BRANCH RESIDUE CHEMISTRY									
	P	EEE BRANCH ENVIRONMENTAL CHEMISTRY									
	Q	TOXICOLOGY BRANCH HUMAN SAFETY	BEST DOCUMENT AVAILABLE								
	R	EEE BRANCH ENVIRONMENTAL SAFETY									
	S										
	T										
PRODUCT MANAGER SIGNATURE				TYPE OF RESPONSE				CODE			
				(R)							

30

10 JAN 1978

Pierson Laboratories, Inc.
P.O. Box 6503
Leawood, Kansas 66206

Gentlemen:

Subject: Chigg-Away
EPA File Symbol 36864-R
Your application of November 26, 1977

The product referred to above will be acceptable for registration under the Federal Insecticide, Fungicide, and Rodenticide Act; provided, finished labeling is submitted incorporating the following revisions.

"EPA Reg. No. 36864-1" is being reserved for this product. This appear on the finished label. The "Notice of Registration" will be issued when five (5) copies of the acceptable finished (printed) labeling are submitted. Finished labeling is that which will be attached to or accompany the product. Refer to the attached A-79 Enclosure.

To expedite handling, please return the enclosed duplicate copy of this letter with your finished labeling.

This letter does not constitute registration, and the product may not be lawfully marketed in interstate commerce until it is registered.

The submitted accelerated storage stability data is acceptable on an interim basis pending the results of the full 12 month study. The results of the 12 month study must be received by EPA within 2 years after the granting of registration.

BEST DOCUMENT AVAILABLE

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I have enclosed a sheet on type size requirements for your
convenience.

Sincerely,

Timothy A. Gardner
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (WH-567)

WH-567:T.A. Gardner:ld:rm 219WSME:x68816:1/3/78

SUBMISSION REVIEW RECORD				1. REGISTRATION NUMBER				CYCLE	2. DATE RECEIVED		
3. 3CID PUBLICATION NECESSARY				4. PETITION NO.				5. RECEIVED PM TEAM			
6. METHOD OF SUPPORT				7. PRODUCT MANAGER				NO.	8. PROJECTED RETURN		
9. DATE PULLED				10. DATE PUBLISHED				11. ACTION TYPE			
12. OUTGOING DATE				13. REVIEW COMPLETED				14. REVIEW CODE			
<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO				36864 - 00000000				RO1	12/14/77		
<input type="checkbox"/> 2A <input type="checkbox"/> 2B <input type="checkbox"/> 2C				JAG				150	11/4/78		
52				52				52			
REV. SEQ.	REVIEW TYPE CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER				COM-MENT CODE	DATE REVIEW COMPLETED		
A		REVIEWABILITY TEAM	SVIH	Susan D. Hunkel				RL	12/22/77		
B		PRODUCT MANAGER TEAM EFFICACY REVIEW	JBR					NAR	12/29/77		
C		PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW									
D		PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW									
E		PRODUCT MANAGER TEAM RESUBMISSION REVIEW	JBR					NAR	12/29/77		
F		PRODUCT MANAGER									
G		INTERAGENCY REFERRAL									
H		COST-BENEFIT REVIEW									
I		PUBLIC COMMENTS REVIEW									
J		EEE BRANCH INSECTICIDE EFFICACY									
K		EEE BRANCH HERBICIDE EFFICACY									
L		EEE BRANCH FUNGICIDE EFFICACY									
M		EEE BRANCH RODENTICIDE EFFICACY									
N		EEE BRANCH DISINFECTANT EFFICACY									
O		CHEMISTRY BRANCH RESIDUE CHEMISTRY									
P		EEE BRANCH ENVIRONMENTAL CHEMISTRY									
Q		TOXICOLOGY BRANCH HUMAN SAFETY									
R		EEE BRANCH ENVIRONMENTAL SAFETY									
S											
T											
PRODUCT MANAGER SIGNATURE				TYPE OF RESPONSE				CODE			

Product ingredient source information may be entitled to confidential treatment

REPORT OF TELEPHONE CALL OR VISITOR			NOTE: Complete this form. Write "NA" where not applicable.
INCOMING CALL		VISITOR	DATE 1/10/78
OUTGOING CALL		CONGRESSIONAL	TIME OF CALL
NAME AND ADDRESS OF CALLER OR VISITOR Mr. James Bendure Pierson Labs., Inc. Leawood, KS			PHONE NO. (Include Area Code or IDS No.) (816) 753-4600 x276
			REGISTRATION, ID NO. OR FILE SYMBOL 36864-R
			DATE OF LATEST SUBMISSION 11/26/77
BRIEF SUMMARY OF CONVERSATION This call is in reference to an earlier question by Bendure, thru Tom Behon (agent), on whether they could change the sulfur declaration in the ingred. statement to [REDACTED]			
ACTION TAKEN OR RECOMMENDED Asked chemist - no; [REDACTED] [REDACTED] [REDACTED] really not a legitimate chemical name. They could use just "sulfur" tho. He will keep "precipitated sulfur" Also, he asked about estab. no. He doesn't have one for this product. I explained what they were and how to get one, and that they must appear either on the label or container.			
RECORDED BY (Name) JSC/Conberger		REFERRED TO (Name) 181	

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K/3

X

34

November 26, 1977

Timothy A. Gardner
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (WH-567)

Dear Mr. Gardner:

Subject: Chigg-Away
EPA File Symbol 36864-R

In response to your letter of November 16, 1977 a new Confidential Statement of Formula is herewith submitted. Also enclosed are the results of the accelerated stability study. The changes suggested for the label format have been made and a revised label statement is enclosed.

You have made reference to enclosures in your letter. They were apparently omitted since none were received. The enclosure which would have indicated appropriate type size for the product label size would have been beneficial, however, be advised that the product label size will not exceed the demensions allowable for the type size specified on the proposed label format.

Sincerely,

James D. Bendure
James D. Bendure
Pierson Laboratories, Inc.

BEST DOCUMENT AVAILABLE

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FRONT PANEL

NEW

Fights Chiggers 2 Ways!

C H I G G - A W A Y

1. REPELS Chiggers!
2. RELIEVES Itching of Chigger Bites!

ACTIVE INGREDIENTS

Precipitated Sulfur.....10.0%
Benzocaine....., 0.5%

INERT INGREDIENTS.....89.5%

Keep Out of Reach of Children (6 point)

CAUTION (10 point) See Back Panel for Additional Precautions

4 fluid ounces

BACK PANELCHIGG-AWAY

For External Use Only-Do Not Take Internally

Precautionary Statements

Hazards to Humans

Keep away from eyes or other mucous membranes. Not for prolonged use. If the condition for which this preparation is used persists or if a rash or irritation develops, discontinue use and consult physician.

Not to be used in infants younger than two years because of risk of methemoglobinemia.

Directions For Use General Classification

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

WORKS TWO WAYS

1. Effectively repels chiggers! Apply around ankles, waist and to skin under all areas of tight fitting clothing and around all openings in outer clothing. Re-apply after heavy exercise or swimming.
2. Relieves itching and discomfort of bites from chiggers, mosquitoes, ticks and biting flies. The unique action of Chigg-Away lotion carries prompt relief to the source of irritation. Provides soothing relief from itching. Apply topically and rub in well as needed.

Disposal (6 points)

Do not reuse empty container. Wrap container and put in trash collection.

Pierson Laboratories, Inc.
P.O. Box 6503
Leawood, Kansas 66206

BEST DOCUMENT AVAILABLE

EPA Reg. No. 149
EPA Est. No.

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OK

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NOV 16 1977

Pierson Laboratories, Inc.
c/o Mr. James Bendure
2304 West 105
Leawood, KS 66206

Gentlemen:

Subject: Chigg-Away
EPA File Symbol 36864-R
Your applications of August 26, 1977 and September 7, 1977

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is not acceptable, for the reasons given below.

1. No formula statement for sulfur was found with the above submission as so claimed. However, we do have one from [REDACTED]

2. Since the formula will be changed to reflect impurities in the sulfur a new Confidential Statement of Formula is required. Use the enclosed 8570-4 form. Be sure to include the trade name and EPA Reg. No. of the sulfur product you plan to use, and all the other information on your formula dated March 25, 1977.

3. The analytical methods for determining sulfur and benzocaine content in the formula are acceptable.

4. We note that accelerated storage stability tests have been initiated, and that we will hold product registration until these tests are found acceptable.

5. On the front panel of the label make the following changes:

a. The ingredient percentages should be all carried out to the same decimal place (10.0%) and aligned.

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- b. Add after CAUTION "See back panel for additional precautions."
 - c. Since we do not know of the exact size of the label we cannot comment on the proposed type sizes. Refer to the enclosure for appropriate sizes.
6. On the back panel, make the following changes:
- a. After "Directions For Use" add "General Classification."
 - b. The type size of "DISPOSAL" must be the same as that for the child precaution.
7. Be reminded that as mentioned in our December 23, 1975 letter to you this product is also a drug because of its itch relief claim, and therefore is subject regulations FDA may have. Also in that letter, you were informed that the FDA has deferred a review of this preparation to the Over-the-Counter Drug Review (OTC) because of a present lack of information on this preparation and its claims. So, during this interim, until a final determination has been made by FDA, they permit this product to be marketed, with EPA's concurrence. Thus, the marketing of this product once EPA has issued registration is solely your responsibility with the realization that the results of the OTC Drug Review by FDA may affect the continued marketing of this product.

Sincerely,

Timothy A. Gardner
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (WH-567)

WH-567:T.A. Gardner:ld:rm 219WSME:x68816:11/9/77

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SUBMISSION REVIEW RECORD				1. REGISTRATION NUMBER				CYCLE	2. DATE RECEIVED		
3. 3C/D PUBLICATION NECESSARY				4. PETITION NO.				5. RECEIVED PM TEAM			
6. METHOD OF SUPPORT				7. PRODUCT MANAGER				NO.	8. PROJECTED RETURN		
9. DATE PULLED				10. DATE PUBLISHED				11. ACTION TYPE			
12. OUTGOING DATE				13. DATE REVIEW COMPLETED				14. PRODUCT MANAGER SIGNATURE			
<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO				36864 - R					090877		
<input type="checkbox"/> 2A <input type="checkbox"/> 2B <input type="checkbox"/> 2C				TAG				15	MO DAY YR		
								52	MO DAY YR		
REV. SEC.	REVIEW TYPE CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER				COM-MENT CODE	DATE REVIEW COMPLETED		
A		REVIEWABILITY TEAM	SIV/H	Susan V. Hummel				035	100677		
B		PRODUCT MANAGER TEAM EFFICACY REVIEW	JBR					003	1101977		
C		PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW									
D		PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW									
E		PRODUCT MANAGER TEAM RESUBMISSION REVIEW									
F		PRODUCT MANAGER									
G		INTERAGENCY REFERRAL									
H		COST-BENEFIT REVIEW									
I		PUBLIC COMMENTS REVIEW									
J		EEE BRANCH INSECTICIDE EFFICACY	JBR					HAR	100577		
K		EEE BRANCH HERBICIDE EFFICACY									
L		EEE BRANCH FUNGICIDE EFFICACY									
M		EEE BRANCH RODENTICIDE EFFICACY									
N		EEE BRANCH DISINFECTANT EFFICACY									
O		CHEMISTRY BRANCH RESIDUE CHEMISTRY									
P		EEE BRANCH ENVIRONMENTAL CHEMISTRY									
Q		TOXICOLOGY BRANCH HUMAN SAFETY									
R		EEE BRANCH ENVIRONMENTAL SAFETY									
S											
T											
PRODUCT MANAGER SIGNATURE				TYPE OF RESPONSE				CODE			

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August 26, 1977

Mr. Douglas D. Campt
Acting Director
Registration Division (WH-567)
United States Environmental Protection Agency



Dear Mr. Campt:

Subject: CHIGG-AWAY
EPA File Symbol 36864-R

In response to your letter dated June 17, 1977 and received July 6, 1977 I have outlined for you the action that has been taken on each point or question listed.

- (1) (a) Source of chemical for each active ingredient. [REDACTED]
[REDACTED]
- (b) Enclosed find formula statement for benzocaine and sulfur.
- (c) Included in formula statement for benzocaine.
- (d) Analytical methods for determination of sulfur and benzocaine content in formulation are enclosed.
- (e) Accelerated stability study is being initiated. Test data will be immediately submitted upon completion.
- (f) Formula will be changed to reflect impurities in sulfur. i.e.-
[REDACTED]
Please note this change on our application in your files.

(2) Following telephone conversation with your department, the requested literature references are enclosed.

(3) The checking of 2A was an unintentional error. Thank you for bringing this to our attention. The revised Offer to Pay Statement has been completed and is enclosed.

(4) The revised label format is enclosed and reflects the requested additions and changes.

During the telephone conversation with your department regarding the efficacy studies, I requested an extension of 75 days on our application. The request was granted and I was informed it would be so noted in our file. I would appreciate your acknowledgement of this extension.

Sincerely,

James D. Bendure
James D. Bendure

Pierson Laboratories, Inc.

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OFFER TO PAY STATEMENT

Name and address of Applicant:

Pierson Laboratories

2304 W. 105

Leawood, Ks. 66206

DATE OF STATEMENT: 3/12/77

SUBJECT: Name of Pesticide Product: Chigg-Away

EPA REGISTRATION NUMBER/FILE SYMBOL: 36864-R

I hereby offer to pay reasonable compensation to the extent provided under Section 3(c)(1)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, and in accordance with the Regulations and Guidelines published thereunder for use of any test data which has been submitted to the U.S. Environmental Protection Agency in support of an application for the registration of a pesticide for the first time on or after January 1, 1970 and which may be used in support of the registration application for the subject pesticide.

James D. Bendure
Signature of Applicant

James D. Bendure
Name of Applicant

Vice-President
Title of Applicant

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FRONT PANEL

NEW

Fights Chiggers 2 Ways!

CHIGG - A W A Y

1. REPELS Chiggers!
2. RELIEVES Itching of Chigger Bites!

ACTIVE INGREDIENTS

Precipitated Sulfur.....10%
Benzocaine.....0.5%

INERT INGREDIENTS.....89.5%

Keep Out of Reach of Children (6 point)
CAUTION (10 point)

4 fluid ounces

BACK PANELCHIGG-AWAY

For External Use Only-Do Not Take Internally

Precautionary Statements
Hazards to Humans

Keep away from eyes or other mucous membranes. Not for prolonged use. If the condition for which this preparation is used persists or if a rash or irritation develops, discontinue use and consult physician.

Not to be used in infants younger than two years because of risk of methemoglobinemia.

Directions For Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

WORKS TWO WAYS

1. Effectively repels chiggers! Apply around ankles, waist and to skin under all areas of tight fitting clothing and around all openings in outer clothing. Re-apply after heavy exercise or swimming.
2. Relieves itching and discomfort of bites from chiggers, mosquitoes, ticks and biting flies. The unique action of Chigg-Away lotion carries prompt relief to the source of irritation. Provides soothing relief from itching. Apply topically and rub in well as needed.

DISPOSAL (6 points)

Do not reuse empty container. Wrap container and put in trash collection.

Pierson Laboratories, Inc.
~~P.O. Box 2284, St. Louis~~ P.O. Box 6503
Leawood Overland Park, Kansas 66206

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EPA Reg. No. 155
EPA Est. No.

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PREVENTION AND CONTROL
OF CHIGGERS

TO PREVENT CHIGGER BITES: Dust on skin of arms and legs, and apply it on clothing likely to be exposed to chiggers.

CHIGGER CONTROL: The contents of this can will cover from 1500 to 2000 square feet applied either as a dust or spray. Best used as a wettable spray, applied to entire lawn, flower garden, shrubs and any place where chiggers may be hiding or where people contact foliage. Make a repeat application in about two weeks to kill those missed before, or those crawling in over new, unsprayed foliage.

PRECAUTIONS

Do not apply on foliage within one week after applying any spray containing an oil emulsion. Do not spray an oil emulsion on plants within 30 days after spraying or dusting with sulphur. Sulphur may burn foliage if applied when the temperature is over 90 degrees. Do not apply sulphur to cucumbers, melons, and certain other cucurbits.

NOTICE: Buyer assumes all risk and liability of use, storage and/or handling of this material not in accordance with the terms of his label.

patterson's
greenUP

**NATURAL
FUNGICIDE-MITICIDE
WETTABLE SULPHUR**

USE AS DUST OR LIQUID SPRAY

ACTIVE INGREDIENTS:

*Sulphur 95%

INERT INGREDIENTS 5%

TOTAL 100%

*95% of this sulphur will pass through a 325 mesh screen.

CAUTION:

Keep Out of Reach of Children.
See other cautions on side panel.

Net Contents 1½ Lbs.

E.P.A. Reg. No. 2169 232 1-73

Distributed by

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DIRECTIONS

USE FOR: BROWN ROT AND PEACH SCAB on Peaches. LEAF SPOTS on Roses, Phlox, Hollyhocks. RUST on Chrysanthemums, Carnations, Snapdragons, Asparagus, Beans. POWDERY MILDEW on Roses, Lilacs, Chrysanthemums, Dahlias, Calendulas, Delphinium, Phlox, Sweet Peas, Peas, Beans, Currants, Gooseberries, Peaches. MITES on Almonds, Avacados, Beans, Cotton, Currants, Evergreens, Gooseberries, Figs, Peas, Plums, Prunes, Walnuts, Citrus Fruit. THRIPS on Citrus Fruits.

USED AS A LIQUID SPRAY

Mix 3-4 tablespoonfuls of Wettable Dusting Sulphur with equal parts of water, make a thick paste and slowly add to one gallon of water. Apply with sprayer, but keep solution agitated.

USED AS A DUST

Wettable Dusting Sulphur can be used in its present form, either in a hand duster or punch out holes in top of can and use as a shaker to apply directly on foliage, or parts to be protected.

WHEN TO APPLY

Apply in early morning or in evening when air is still. Thoroughly cover all plant surfaces. Repeat applications at 7 to 10 day intervals during spring and summer. Remember, it should be used to prevent insects and plant diseases rather than to cure them.

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THE UNIVERSITY OF KANSAS MEDICAL CENTER
COLLEGE OF HEALTH SCIENCES AND HOSPITAL

RAINBOW BOULEVARD AT 39TH • KANSAS CITY, KANSAS 66103

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SCHOOL OF MEDICINE
SCHOOL OF NURSING
SCHOOL OF ALLIED HEALTH
UNIVERSITY HOSPITAL

April 2, 1976

DEPARTMENT OF PHARMACOLOGY
(913) 831-7140

Mr. H. Harrison
Registration Division
Insecticide Rodenticide Branch
U.S. Environmental Protection Agency
Washington, D.C.

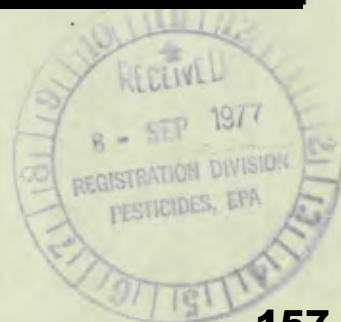
Dear Mr. Harrison:

Mr. Jim Bendure of the Pierson Laboratories has asked me for an opinion on the potential toxic effects of their product, CHIGG AWAY. My understanding is that this product would contain 10% precipitated sulfur, 0.5% benzocaine and small amounts of [REDACTED]

The major ingredient in this product, precipitated sulfur, has a very low toxicity even when taken internally (mild laxative effect due to conversion of sulfur to alkali sulfides) and is virtually non-toxic when applied externally. It has been widely used as a mild antiseptic and parasiticide in lotions, creams, ointments, and other forms and to my knowledge has none of these formulations produced toxic effects. There were some reports of toxicity following the use of a precipitated sulfur-lead acetate preparation which was used to darken gray hair, but the toxic effects in these cases were shown to be due to the lead. Contact dermatitis (dermatitis venenata) has also been reported with some sulfur containing preparations which contain sensitizers or irritants in addition to the sulfur.

Benzocaine (ethyl aminobenzoate), the other active ingredient in this preparation, also has a long history of safety when used as a surface anesthetic in concentrations of up to 20%. When benzocaine containing formulations are applied to abraded skin or in situations where absorption can occur, methemoglobinemia may be produced (and has been reported in infants). However, with the concentration proposed for this preparation (0.5%), I would not anticipate any toxic manifestations.

The remaining ingredients in this formulation are present in low concentration and would not be expected to produce toxic effects. Several of these agents [REDACTED] are accepted food chemicals (listed in Food Chemical Codex) and the rest of the ingredients [REDACTED] are all USP chemicals.



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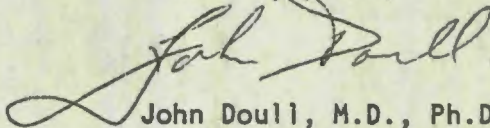
Inert ingredient information may be entitled to confidential treatment

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Mr. H. Harrison
April 2, 1976
Page 2

It appears to me, therefore, that this product would not present any toxicity problems particularly when used externally as directed. On a poison control basis, I would classify this product as non-toxic and would, therefore, have no concern about its over-the-counter use by the general public.

Sincerely yours,



John Doull, M.D., Ph.D.
Professor of Pharmacology and Toxicology
Chairman, Poison Control Center, KUMC

JD/mk

CC: Mr. Jim Bendure

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CIRCULAR NO. 77.

United States Department of Agriculture,

BUREAU OF ENTOMOLOGY,

L. O. HOWARD, Entomologist and Chief of Bureau.

HARVEST MITES, OR "CHIGGERS."

By F. H. CHITTENDEN,

Entomologist in Charge of Breeding Experiments.

Residents of the South and of the more southern portion of many of the Central States, and especially visitors to these sections, are often subject to great annoyance due to the attacks of minute creatures popularly known as "chiggers"¹ and "red bugs," and, incorrectly, as ticks.

These pests are the larval or six-legged forms of harvest mites of the genus *Trombidium*, the adults of which have eight legs. They are troublesome because of their unpleasant habit of burrowing under the skin of human beings. This habit is not normal, and as a consequence the mites die, and their presence under the epidermis gives rise to irritation and inflammation of varying intensity.



FIG. 1.—*Trombidium*: Larva, highly magnified (from Banks).

For present purposes we may consider the harvest mites as a class. In figures 1 and 2 illustrations of some common forms are furnished. The larval harvest mites are of microscopic size, blood red, and shaped somewhat like a common tick, being nearly as broad in front as behind. They belong to the order Acarina and are not true insects (Hexapoda), but are members of a distinct class (Arachnida) along with ticks, spiders, and the like. The parent mites are predaceous on true insects. As early as 1834 Mr. A. L. Dugès² made observations on these mites, which, as previously stated, have six legs in the immature or parasitic stage while the adults have eight. The adults are of different shades of red and are quite visible. Many persons are familiar with the appearance of the young of certain species,

¹The name "chigger" or "jigger" is evidently a corruption of chigoe, the pernicious sand-flea (*Sarcophylla penetrans* L.) of tropical America, a true flea, which crawls under the toe nails of man, producing painful sores which may result seriously if neglected.

²Annales des Sciences Naturelles, Vol. I, ser. 1, p. 36; see also P. Megnin, l. c., Vol. IV, ser. 6, pp. 4-20, 1876, and Murray's Aptera, pp. 120-133.

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as they occur on the under surface of the bodies of grasshoppers and harvest spiders or "daddy long legs" (Phalangidae) and under the wings of the house fly. Just what species of harvest mites are troublesome to man in the United States is not known, but one of them, perhaps the commonest, is referred to in literature as "*Leptus*" *irritans* Riley.¹

SYMPTOMS AND MANNER OF ATTACK.

Soon after the harvest mite burrows under the human skin a small red spot appears (evidently the mite itself gorged with human blood), after which the surrounding surface becomes congested, the affected area spreading until it is from less than a quarter to a half or three-fourths of an inch in diameter. This congestion may manifest itself within less than an hour after exposure or may not be apparent for twelve

hours or so, the fever being at its height usually on the second day. The symptoms are apt to be first noticed when the sufferer has removed his clothing at night, or upon awakening from sleep. It sometimes happens that there is little irritation until some time after exposure, but with most persons susceptible to the poison-



FIG. 2.—*Leptus americanus* at left; *Leptus irritans* at right. Highly magnified, dots under anal extremity indicating natural size (after Riley).

ous effects of these mites irritation is first experienced on the second day. The feverish appearance of the afflicted skin area varies according to the susceptibility of the person attacked. Children dwelling or sojourning in mite-infested localities suffer greatly from these pests, experienc-

¹ Riley, Poisonous Insects, Extr. Ref. Handb. Med. Sci., Vol. V, 1887, p. 745.

Leptus is a genus founded on the larval Trombidium. For those who may desire further information in regard to the structure of the adult, the following paragraph is transcribed from "A Treatise on the Acarina or Mites," by Nathan Banks (Proc. U. S. Nat. Mus., Vol. XXVIII, pp. 30, 31, 1904), together with a figure illustrating a common species:

The "harvest mites" * * * are recognized by the body being divided into two portions, the anterior (cephalothorax) bearing the two anterior pairs of legs, the palpi, mouth parts, and eyes. The posterior (abdomen) is much larger and bears the two posterior pairs of legs. The mandibles are chelate, at least there is a distinct jaw or curved spine-like process. * * * The body is covered with bristles or feathered hairs, according to the species. The palpi are five jointed, quite prominent, often swollen in the middle, the penultimate joint ending in one or two claws, the last joint (often clavate) appearing as an appendage or "thumb" to the preceding joint. The legs are seven jointed. The tarsi terminate in two small claws. The legs are clothed in the same manner as the body. There are two eyes upon each side of the cephalothorax, quite frequently borne on a distinct pedicel. The genital aperture is situate between the hind coxae. The anal opening is smaller than the genital and placed a little behind it.

ing more severe annoyance than adults, and young women as a rule suffer more than older persons. People with thin, delicate skin and florid complexion are most afflicted by the mites, and with them the congested red spots are proportionately larger and more inflamed and irritating.

Many persons, however, as, for example, permanent residents of infested regions, and particularly farm laborers, seem to be practically proof against the toxic effects of harvest mites and go with impunity into places overrun with them. This immunity to poisoning is obviously due to two causes: (1) To outdoor work which toughens the person's skin, especially such portions of the arms and legs as are much exposed to the sun and weather; and (2) to inoculation, due to frequent infection.

The inflamed spots due to the presence of the mites under the human cuticle are often diagnosed as hives, nettle-rash, urticaria, or the "weals," and resemble closely those produced on many persons by the "bites" of fleas and some mosquitoes, but on the second or third day each of the mite-infested areas is usually found surmounted at the middle by a minute vesicle or water blister. This is obviously the most important characteristic of harvest-mite attack. After the subsiding of the inflammation and itching, which takes place in a few days, a small scale or scab frequently forms, leaving on some persons a scar which does not wholly disappear in extreme cases for weeks. The mites naturally attack first those portions of the body which are most exposed—those nearest the ground. They crawl into the stockings and penetrate the skin about the ankles, frequently below the shoe tops, and are usually found most numerous below the knee. According to the late Dr. John Hamilton, a physician as well as entomologist, the harvest mites enter the larger sweat tubes or pores of the skin, and as these tubes are very tortuous, the progress of the mites is necessarily slow, from eighteen to thirty-six hours being required for them to reach the end. When the lesions caused by these mites are unusually numerous, the sufferer becomes feverish, and sleep is much disturbed. Sometimes the afflicted one becomes frantic and lacerates his flesh by too vigorous and frequent scratching. Erysipelas is known to follow severe attacks, and death resulting from blood poisoning is recorded. These more serious results of infestation are, however, exceptional and, as with the fatalities which in rare cases follow the ordinarily merely painful or annoying "bites" of many insects, undoubtedly point to an impurity of the blood.

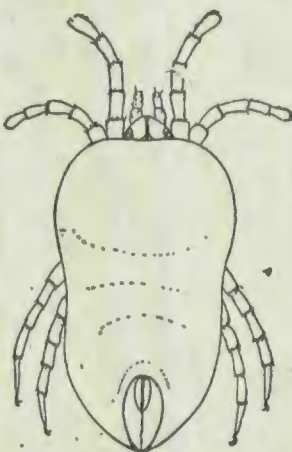


FIG. 3.—*Trombidium*: Adult, highly magnified (from Banks).

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HABITAT.

Harvest mites are most abundant in damp locations, along the borders of streams and other bodies of water, and on the edges of forest and woodland. They occur also on trees and shrubbery, evidently affecting the lower surface of the leaves, from which they drop off when these are rudely shaken, and find lodgment on the neck or other exposed parts of the body. Riley describes "*Leptus americanus*" as affecting chiefly the scalp and armpits. In places infested by harvest mites it is a matter of danger to sit down or lie in the grass and herbage for any length of time, as the mites will then have easy access to almost any portion of the body. As a rule these creatures appear to be dependent on the shade and not to live in the direct sunlight, but some forms occur in sunny locations.

These mites are most abundant and troublesome in the tropics, and become less numerous as we go northward. They are generally distributed in the Gulf States, up the Mississippi River to Missouri and Illinois, and through the Atlantic Coast States to New Jersey. The writer has personal knowledge of their occurrence in troublesome abundance as far north as Monmouth County, N. J., near the central line of the State, but they appear to be unknown in New England or north of latitude 40° in the East. It is probable that these mites occur northward of Monmouth County, as there is a report of infestation on Long Island.

During the summer of 1906 more complaint than usual was received of harvest mites, evidently due to the extremely warm and humid weather which prevailed over the districts affected by these pests.

A communication was received August 24 from a correspondent at Oregon, Ogle County, Ill., of a plague of chiggers in that vicinity, on the hillsides of the banks of the Rock River, 200 feet high. This locality is west and a little north of Chicago and is evidently the northernmost point of which we have actual knowledge of the occurrence of these mites at the present time.

Harvest mites are well known in England and Scotland under this name and as "gooseberry bugs." On the continent of Europe, also, they are abundant, especially in Belgium and the Netherlands, in parts of Germany, and in France. Indeed, in some of these countries they have at times caused considerable annoyance to the peasantry, whom they have hindered or prevented in the harvesting of certain crops. The mites are troublesome, too, in tropical America, in the West Indies, and in Japan.

LIFE HISTORY.

The life history of a harvest mite, as related by Mr. Banks, is substantially as follows: The female lays her eggs in or upon the ground, sometimes to the number of 400 in one place. The eggs are usually

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brown and spherical and have been considered by some early writers as fungi. The chorion or outer skin splits soon after the eggs are deposited, dividing the eggs into halves and exposing the pale vitelline membrane. The larva when hatched is circular or ovoid in outline, and each of its three pairs of legs is tipped with two or three prominent claws. After the larva has become attached to its insect host it elongates and becomes swollen with food. When full fed it drops off, seeks a convenient shelter, and gradually changes in shape without molting. The new parts are formed under the larval skin, which after a few weeks cracks and discloses the adult Trombidium. The mature harvest mite is predaceous, wandering about and feeding on aphides, small caterpillars, and, in the case of one species, on the eggs of grasshoppers or locusts. It hibernates in the soil or in other sheltered locations and in the spring deposits its eggs. There appears to be a single generation produced each year. Only a few forms have been reared. The larva of one occurs commonly on the house fly in autumn.

REMEDIES.

Preventive.—As harvest-mite infestation is usually contracted by walking or working among blackberry and other shrubbery which harbors them, or by walking, sitting, or lying among grasses or similar herbage along streams or pools on the edges of marshes or under trees near such places, it is obvious that the best means of prevention is the avoidance of exposure by susceptible persons. If, however, a bath is taken in hot water, or water containing salt or strong soap, within a few hours after exposure, no ill effects will be experienced. After a longer exposure a bath has practically no effect, and direct remedies are necessary.

Sulphur is a sovereign remedy for mites and is the best preventive of attack. When exposure is unavoidable and where vegetation is not more than 2 or 3 feet high, a sure preventive is found in sifting flowers of sulphur into the underclothes from a little above the knee downward and into the shoes and stockings, or it may be rubbed over legs and ankles. Naphthaline has been successfully used in the same manner in Mexico by Dr. L. O. Howard and in Cuba by Mr. E. A. Schwarz. While the sulphur, being inodorous and perfectly effective, is undoubtedly preferable against harvest mites alone, naphthaline is a safeguard against various forms of man-infesting tropical insect pests. Vaseline, pure or mixed with sulphur, will serve the same purpose, but is not so agreeable on account of its oily nature and the certainty of its soiling the clothing.

For most localities these precautions are to be observed through the months of July, August, and a part of September. The mites are seldom bothersome in early June or as late as October, but in exception-

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Topical applications.—If exposure has been unwittingly incurred or precautions have been neglected and the characteristic irritation has set in, warning the patient of trouble to come, a counterirritant or cooling lotion should be applied directly to the affected parts. For this purpose moderately strong ammonia, applied when the symptoms are first manifest, has offered the best results, and the writer recommends it above all other direct remedies. Bicarbonate of soda or common cooking soda or saleratus may be substituted in supersaturated solution. Similar alkaline solutions would probably also serve in counteracting the insect poison, which is acid. These substances should be applied liberally until the irritation subsides. Some persons have testified to the value of a 10-per-cent dilution of carbolic acid. Alcohol, camphor, essence of peppermint, and similar preparations are very "cooling," but afford, as a rule, only temporary relief. A dilute tincture of iodine or colloidion applied lightly to the affected parts is a good remedy in case of severe suffering. The latter acts by protecting the "sore" spots from the air.

Destruction of the mites in the field.—Much complaint has been made of the presence of harvest mites on lawns and in vegetation in country grounds and along pathways and roadsides, and information has been solicited by many, including officers of country clubs and the like, for methods of eliminating the mites from such locations. This can be accomplished by keeping the grass, weeds, and useless herbage mowed as closely as feasible; so as to expose the mites to the sun. In some cases this can be facilitated by dusting the grass and other plants, after cutting, with flowers of sulphur or by spraying with dilute kerosene emulsion in which sulphur has been mixed. Grasses on the borders of ponds frequented by cattle, wild blackberry bushes, and similar plants should also be cut down and destroyed in the vicinity of houses and where children and older persons are liable to mite infestation by passing through them. Well-cultivated fields kept free from weeds are not infested with "chiggers," and in the course of time, perhaps a year or two, the measures prescribed, if carefully carried out in grassy locations, should also entirely free these from the pests.

Approved:

JAMES WILSON,

Secretary of Agriculture.

WASHINGTON, D. C., September 29, 1906.



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X/20



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HARVEST MITES.

with a great racket they all rose together like a flock of blackbirds and returned to their haunts among the cedars far up the cañon. For some time a pair of mallard ducks had been circling about as though looking for a place to alight, and finally they selected a bend in the creek just in front of me. Above the ridge beyond the creek, a turkey buzzard was floating listlessly in the morning sun, apparently without the least exertion on his part. I watched him carefully for several moments as he circled about, but could not detect the slightest motion in his wings.

One other bird I saw here to which is attached a good deal of interest, the white-necked crow (*Corvus cryptoleucus*). I have found these birds common along the base of the Rocky Mountains, from Cheyenne at the north, to Trinidad at the south; and from the Snowy Range, to a point thirty miles out on the plain, yet Mr. Ridgway writes me that these birds "are entirely out of their previously known range." I strongly suspect that this bird has been mistaken by naturalists, who have ornithologized in this section, for the common American raven (*Corvus carnivorus*), since it seems to me impossible that any one should remain here any length of time without seeing it; still the Western bluebird (*Sialia Mexicana*), and several other birds which are equally abundant here, are in the same predicament. The raven is said to be common in Colorado, but during a year spent in collecting in different parts of the territory, I have seen but a single pair!

HARVEST MITES.

BY PROF. C. V. RILEY.

IN the "American Entomologist" (vol. 1, no. 5) an account was given of the eight true insects, and of some other ringed animals or articulates, known to be parasitic on man. The insects are, the head-louse (*Pediculus humanus* Linn.), the body-louse (*Pediculus cervicalis* Linn.), the crab-louse (*Pediculus pubis* Linn.), the human bot-fly (*Æstrus hominis* Gmelin), the common flea (*Pulex irritans* Linn.), the chigoe (*Pulex penetrans* Linn.), the common bed-bug (*Acanthia lectularia* Linn.) and the big bed-bug (*Conorhinus sanguisuga* Linn.).

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The only mite that is known to attack man, and whose appearance is at all familiar, is the itch mite (*Acarus scabiei* Linn.). We have, however, in the southwestern States, two other mites which cause great annoyance from harvest time till into October, to people who frequent the rank herbage and grass, in our forest openings or along our rivers. Both of them are six-legged, reddish, microscopic specks, and both are popularly termed jiggers; but as this term is universally applied to the more dangerous *Pulex penetrans* (a true flea occurring in Central America but not in the United States), and as a European mite (*Leptus autumnalis*), having similar habits to ours, is there popularly called "harvest bug," we may apply to our species the term "harvest mites."

Before we can talk intelligently and definitely of anything that moves or has a being upon our earth, it must receive some scientific appellation. According to my friend, A. S. Packard, Jr., and from our present knowledge of the transformation of mites, we may very plausibly conclude that these six-legged forms are but the young of some eight-legged form such as *Trombidium*, to which belongs our common "red spider." Now it is contrary to all scientific usage to name and describe a species from its immature characters; but the older authors not only described these six-legged mites as perfect animals, but referred the different forms to different genera. Therefore, as it is important that such common and annoying pests should have a "local habitation and a name," and as they are so far only known in the six-legged state, I shall provisionally, and for the sake of convenience, name them. Should any future arachnologist learn the true life history of either, he may, of course, recognize or reject these names as he sees fit.

*The American Harvest mite** (*Leptus Americanus?* n. sp. Fig. 5a).—This species is barely visible with the naked eye, moves readily and is found more frequently upon children than upon adults. It lives mostly on the scalp and under the arm-pits, but is sometimes found on the other parts of the body. It does not bury itself in the flesh, but simply insinuates the anterior part of its body just under the skin, thereby causing intense irritation, followed by a little red pimple. As with our common ticks, the

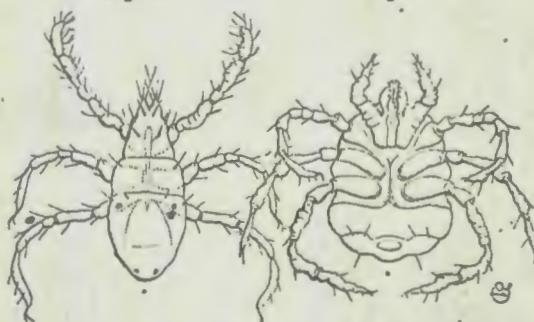
*Color brick-red, slender, ovate, the narrow, anterior end blind, and furnished with stiff, converging setae. Six-legged; legs long, the front pair blunt and slightly thickened at tip where they are incurved and thickly armed with stiff hairs; the others rather longer, and terminating in a stiff, curved, fuscate claw. Average length .008 inch.

irritation lasts only while the animal is securing itself, and its presence would afterwards scarcely be noticed but for the pimple which results.

*The Irritating Harvest mite** (*Leptus irritans*, n. sp. Fig. 5b). This is the more troublesome and, perhaps, better known of the two, causing intense irritation and swelling on all parts of the body, but more especially on the legs and around the ankles. Woe betide the person who, after bathing in the Mississippi anywhere in this latitude, is lured to some green dressing-spot of weeds or grass! He may, for the time, consider himself fortunate in getting rid of mud and dirt, but he will afterwards find to his sorrow that he got hold of something far more tenacious, in these microscopic harvest mites. If he has obtained a good supply of

Fig. 5a.

Fig. 5b.



Harvest Mites.

them, he will, in a few hours, begin to suffer from severe itching, and for the next two or three days he will be likely to scratch until his limbs are sore.

With the strong mandibles, and the elbowed maxillæ, which act like arms, this mite is able to bury itself completely in the flesh, thereby causing a red swelling with a pale pustulous centre containing watery matter. If, in scratching, the person affected is fortunate enough to remove the mite before it enters, the part soon heals. But otherwise the irritation lasts for two, three or four days, the pustulous centre reappearing as often as it is broken.

*Color brick, or blood-red; of tick-like form, being nearly as broad in front as behind; six-legged, the legs terminating in two stiff hairs; a strong pair of elbowed maxillæ, recalling a fourth pair of legs, and similarly terminating in two hairs; mandibles more or less distinctly tridentate at end inside. Length .01 inch.



THE GENETIC RELATIONS OF THE CETACEANS.

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The animal itself, on account of its minute size, is seldom seen; and the uninitiated, when first troubled with it, are often alarmed at the symptoms and at a loss to account for them. Fortunately, these little plagues never attach to persons in such immense numbers as do sometimes young or so-called "seed" ticks; but I have known cases where, with irritation and consequent scratching, the flesh had the appearance of being covered with ulcers; and in some localities, where these pests most abound, sulphur is often sprinkled, during "jigger" season, in foot-gear as a protection.

Sulphur-ointment is the best remedy against the effects of either of these mites, though when that cannot be obtained, saleratus water, and salt water will partially allay the irritation.

The normal food of either must, apparently, consist of the juices of plants, and the love of blood proves ruinous to those individuals who get a chance to indulge it. For unlike the true chigoe the female of which deposits eggs in the wound she makes, these harvest bugs have no object of the kind, and, when not killed at the hands of those they torment, they soon die—victims to their sanguinary appetite.

ON THE GENETIC RELATIONS OF THE CETACEANS. AND THE METHODS INVOLVED IN DISCOVERY.

BY THEODORE GILL, M.D., PH.D.

In a "Synopsis of the Primary Subdivisions of the Cetaceans," published in 1871,* I ventured some remarks on the apparent genetic relations of the Cetaceans, and observed that "between the Carnivores and the Cetaceans of the present age, the gap does indeed appear to be very great, but it is bridged over, to a very considerable extent, by the Zeuglodonts of the Tertiary epoch, . . . and from the Zeuglodont stem have probably descended, in different directions, the toothed and whalebone whales; while the former, in some features, such as the general form of the skull, the teeth, etc., appear to deviate less from ordinary mammals; the latter, in other respects, but especially in the development of

*Proceedings and Communications Essex Inst., vol. vi, pp. 121-123.



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The Trombidiidæ, or Harvest Mites

In many parts of this country it is impossible for a visitor to go into the fields and, particularly, into berry patches and among tall weeds and grass in the summer or early fall without being affected by an intolerable itching, which is followed, later, by a breaking out of wheals, or papules, surrounded by a bright red or violaceous aureola, (fig. 43). It is often regarded as a urticaria or eczema, produced by change of climate, an error in diet, or some condition of general health.

Sooner or later, the victim finds that it is due to none of these, but to the attacks of an almost microscopic red mite, usually called "jigger" or "chigger" in this country. As the term "chigger" is applied to one of the true fleas, *Dermatophilus penetrans*, of the tropics,

these forms are more correctly known as "harvest mites." Natives of an infested region may be so immune or accustomed to its attacks as to be unaware of its presence, though such immunity is by no means possessed by all who have been long exposed to the annoyance.



44. Harvest mites. (Larvæ of *Trombidium*). After C. V. Riley.

The harvest mites, or chiggers, attacking man are larval forms, possessing three pairs of legs (fig. 44). Their systematic position was at first unknown and they were classed under a special genus *Lepus*, a name which is very commonly still retained in the medical literature. It is now known that they are the larval forms of various species of the genus *Trombidium*, a group of predaceous forms, the adults of which feed primarily on insects and their eggs. In this country the species best known are those to be found late in summer, as larvæ at the base of the wings of houseflies or grasshoppers.

There is much uncertainty as to the species of the larvæ attacking man but it is clear that several are implicated. Bruyant has shown that in France the larvæ *Trombidium inapinatum* and *Trombidium holosericeum* are those most frequently found. The habit of attacking man is abnormal and the larvæ die after entering the skin. Normally they are parasitic on various insects.

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Most recent writers agree that, on man, they do not bore into the skin, as is generally supposed, but enter a hair follicle or sebaceous gland and from the bottom of this, pierce the cutis with their elongate hypopharynx. According to Braun, there arises about the inserted hypopharynx a fibrous secretion—the so-called “beak” which is, in reality, a product of the host. Dr. J. C. Bradley, however, has made careful observations on their method of attack, and he assures us that the mite ordinarily remains for a long time feeding on the surface of the skin, where it produces the erythema above described. During this time it is not buried in the skin but is able to retreat rapidly into it through a hair follicle or sweat gland. The irritation from the mites ceases after a few days, but not infrequently the intolerable itching leads to so much scratching that secondary infection follows.

Relief from the irritation may be afforded by taking a warm salt bath as soon as possible after exposure or by killing the mites by application of benzine, sulphur ointment or carbolized vaseline. When they are few in number, they can be picked out with a sterile needle.

Much may be done in the way of warding off their attacks by wearing gaiters or close-woven stockings extending from ankle to the knee. Still more efficacious is the sprinkling of flowers of sulphur in the stockings and the underclothes from a little above the knee, down. The writers have known this to make it possible for persons who were especially susceptible to work with perfect comfort in badly infested regions. Powdered naphthalene is successfully used in the same way and as Chittenden (1906) points out, is a safeguard against various forms of man-infesting tropical insect pests.

The question of the destruction of the mites in the field is sometimes an important one, and under some conditions, is feasible. Chittenden states that much can be accomplished by keeping the grass, weeds, and useless herbage mowed closely, so as to expose the mites to the sun. He believes that in some cases good may be done by dusting the grass and other plants, after cutting, with flowers of sulphur or by spraying with dilute kerosene emulsion in which sulphur has been mixed. More recently (1914) he calls attention to the value of cattle, and more especially sheep, in destroying the pests by tramping on them and by keeping the grass and herbage closely cropped.

few minutes. This obviates the necessity for towels or cloths.

A word of precaution at this point is advisable. There is a tendency on the part of the men to dip their hands in the cans containing the water rather than to tip the cans and pour the water on their hands. It is obvious, if this is done, that the water soon becomes fouled. This tendency can be guarded

against by proper instruction and by a little sign painted directly on the cans or on a board nearby admonishing the men to "TIP Don't DIP."

We have used this washing device in the field for several months and have found it to be quite satisfactory.

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SULFUR AND SOAP AS EFFECTIVE PROPHYLAXIS AGAINST "CHIGGERS" (RED BUGS) IN THE ARMY

By CAPTAIN ZACHARY J. ROMEO, *Medical Corps, U. S. Army*

'CHIGGERS" (Harvest Mites, Red Bugs, Jiggers, etc.) present a problem to the soldier because his clothes are constantly being infested by contact with brush and grass, and also because his washing time is neither constant nor thorough when "on the move." These organisms, which are larval forms of various species of mites belonging to the family Trombidiidae, have a widespread distribution in the United States in harvest fields, lowlands, mountainous regions, and wherever there is rough growth of weeds and shrubbery. As Doane¹ says: "About the very worst pests of man and domesticated animals are the Harvest-bugs, Red-bugs or Jiggers . . . which, whenever they succeed in finding a host, burrow in and under the skin, causing intolerable itching and sores, the latter caused by the feverish activity of the fingernails of the host. . . . Those who have ever passed through meadows infested with red-bugs will remember the occasion."

Sulfur has been found to be effective in the prophylaxis^{2, 3, 4} and treatment¹ of infestation by "chiggers," and Nolan^{5, 6} has described a "sulfur soap paste lather" which he found "simple, efficient and inexpensive" in the treatment of scabies. This preparation was used in the form of a convenient "applicator" of loosely woven cloth which incorporates pure sulfur and a bland toilet soap. When the applicator or sulfur pad is moistened and applied, a copious foam is produced which evenly distributes the sulfur over the surface of the body. It was decided to test the effectiveness of this form of sulfur application as a prophylaxis against "chiggers" during the Army maneuvers of July and August in Louisiana by means of the following simple experiment.

A company consisting of three sections of approximately equal numbers—34, 38 and 35 men, were allowed to go unprotected on the field for the first two days to make certain of the presence of red bugs in the area. With-



in a few hours it was evident that the organisms were present. The number of bites received was checked by body inspection, and recorded. Mosquito and other bites were eliminated. Each section was then put on a schedule of treatment and the results were re-

cations seemed to ease the itching of the old bites, and apparently kept the incidence of secondary infection to a minimum. It is believed that the cleansing action of the pads was responsible in great measure for this feature. Secondary infection of these bites resem-

TABULATION OF RESULTS

	First Two Days			First Week			Second Week			Third Week		
Section	1	2	3	1	2	3	1	2	3	1	2	3
Number of Men	34	38	35	34	38	35	34	38	35	34	38	35
Pads per 2 Days	0	0	0	2	1	0	2	1	0	0	2	2
Average Number of Bites	7	9	8	2	4	12	3	5	20	8	3	6
Chemical Dermatitis	0	0	0	0	0	0	0	0	0	0	0	0

corded each week. Section 1 was instructed to use one pad⁷ each morning the first and second weeks, and no medication the third week. Section 2 was told to apply one pad on alternate mornings during the first and second weeks, and one pad each morning during the third week. Section 3 was instructed to use no medication during the first and second weeks, and to apply one pad each morning during the third week. The schedule was followed accurately except for an error of $\pm 5\%$ during the second week because of rapid movements of the troops. Old bites were eliminated from subsequent counts. All of the troops were in the same area so that the equalizing factor was constant. The results which demonstrated the effectiveness of the treatment are presented in the table.

Many interesting facts were noted during the experiment. There were no cases of chemical irritation due to prolonged use of sulfur. In fact, the appli-

bles a good case of impetigo, and a decrease in this condition is welcome to anyone. The decrease in the number of bites was remarkable in view of the fact that the soldiers were compelled to wear infested clothing for days at a time without change.

After the first week, many of the new bites were higher on the body, usually around the waist. This was interpreted as resulting from a more thorough application of the sulfur foam to the legs and a less thorough application to the abdomen (the first group of bites was around the legs). There was also some correlation between segregational duties and the incidence of bites—it was lower among truck drivers than the rest of the company. This might have been due to a series of factors—clothes permeated with gasoline, living in trucks the greater part of the day, less contact with grass, etc.

An interesting observation was made

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with regard to the "effective time" factor in treatment. It is significant that one pad each day was more effective than a pad every other day. However, the pad on alternate days did demonstrate its comparative value.

CONCLUSIONS

1. Sulfur applied as lather was found to be highly effective as prophylaxis against "chiggers" (red bugs).
2. Daily application of the sulfur was found to be more effective than treatment on alternate days.
3. The cleansing action of the sulfur lather was of appreciable importance.
4. The superiority of this form of

sulfur over powders, ointments, pastes, etc., is without challenge.

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- Co. A, 106th Med. Regt.,
Camp Blanding, Fla.

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SOAP AND WATER AS A VENEREAL DISEASE PROPHYLACTIC

By CAPTAIN W. A. ANGWIN, *Medical Corps, U. S. Navy*

BUREAU of Medicine and Surgery Circular Letter 4-1 of April 1, 1941 pertaining to methods of control of contagious diseases, states in connection with control of gonorrhea and syphilis: "Personal prophylaxis should be advised and made available for use before or immediately after sexual intercourse to those who expose themselves to infection."

While this obviously is a statement of general policy rather than an expression of exact detail, the question naturally arises as to just what measures of personal prophylaxis are to be advised and how they are to be made available for *immediate* use.

Generally speaking, the scheme of venereal prophylaxis used in the Navy

for the past 30 years has been built up around methods of chemical therapy administered at prophylactic stations on board ship and at naval stations ashore, and in some instances in the cities frequented by naval personnel.

Almost universally, the measures or agents advocated in our educational program and provided for use of exposed individuals consist of a mechanical preventive (condom), and a chemical regime which includes a urethral injection of permanganate of potash solution or a protein silver solution to be held in the urethra for five minutes, followed by an application to the external genitals of a calomel ointment. Men are instructed to go to a prophylactic station as soon as they can after exposure. The

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UNITED STATES DEPARTMENT OF AGRICULTURE



BULLETIN No. 986

Contribution from the Bureau of Entomology
L. O. HOWARD, Chief



Washington, D. C.

December 3, 1921

STUDIES ON THE BIOLOGY AND CONTROL OF
CHIGGERS.

By H. E. EWING, *Specialist in Mites.*

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INTRODUCTION.

Notwithstanding the obvious economic importance of chiggers, and an almost universal acquaintance with their injury, little has been done in the past to ascertain their habits in nature or to find efficient methods for their control. Because of these facts the writer decided early in the season of 1919, with the approval of Dr. L. O. Howard, Chief of the Bureau of Entomology, to begin a series of experiments and observations on their biology and control. The work was started in June of that year and continued until the fall of 1920. For various reasons it was thought advisable to discontinue the work then for some time, hence the results thus far obtained have been prepared for publication. It is the expectation of the writer, in the near future, not only to complete the life history for at least one of our species, but to give a synopsis of the taxonomy and distribution of the species occurring in the United States.

SPECIES CONCERNED.

Years ago C. V. Riley (10)¹ described from this country ("south-western States") two chigger species under the familiar names of

¹ Reference is made by number (italic) in parentheses to "literature cited," page 19.

Leptus americanus and *Leptus irritans*. Although these names have been used frequently in American literature dealing with economic entomology, and the figures of Riley's two species often copied, the present writer is bound to confess that after studying carefully Riley's descriptions and figures and some of his microscope slides (types?) he has been unable to correlate either *americanus* or *irritans* with the two species with which he is familiar. Further than this it can now be fairly definitely stated that *americanus* is not a species of Trombidiidae at all, but is rather a species of the family Erythraeidae, a group to which the genus *Leptus* really belongs, as Riley's

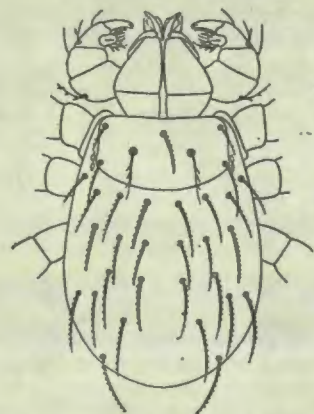


FIG. 1.—Dorsal view of an American chigger (legs omitted), X 150. This drawing was made from specimens in the University of Minnesota collection, which were taken at Lake Minnetonka, Minn.

figure clearly shows. *Leptus irritans* is the larva of a species of Trombidiidae, but the characters given by Riley are not even of generic value; hence it appears that it will never be known certainly what species his *irritans* is.

In New Jersey, Maryland, the District of Columbia, Virginia, and southeastern Iowa there is apparently a single chigger species. The writer has examined many specimens from these sections and finds that they are all the same.

In the northern and western part of the United States there is another very closely related species which has the body shaped exactly like the first mentioned but has more dorsal spines on the abdomen, and fewer branches or barbs on the palpal setae. This is the species

studied by C. W. Howard (6). Specimens have been examined from Minnesota and Kansas.

NOTES ON SEASONAL HISTORY.

Chiggers are especially pests of the summer months, as has long been known, but the period of their activity has not been known even relatively. During the year 1919, at Washington, D. C., the date of the first record of larvæ attaching themselves to man was July 2, and by July 17 larvæ were present in great abundance. On the latter date the writer was severely attacked. During the remainder of July and the whole of August the chigger larvæ continued in great abundance, and almost daily records of their attacks were obtained. In September the attacks were much less severe, yet continued. On September 22 several larvæ attached themselves to man at Chesapeake Beach, Md. No records for the northern part of the United States of chigger attacks in October have been brought to

the writer's attention, but some of the larvæ are probably active during this month.

During the season of 1920 the chiggers were first noted in southeastern Iowa on June 24, when several attached themselves at Keosauqua, where they were present in the State park.

How chiggers pass the late fall and winter is not known, and will not be known until more work is done on the life history of the species and something is known of the nymphal and adult instars.

LOCAL DISTRIBUTION.

Investigations of the last year and a half have thrown much light upon the local distribution of our chiggers, which in turn may furnish the clue for locating their natural hosts and thereby give us an opportunity to rear the larvæ to maturity.

Around Washington, D. C., the chiggers usually have been encountered where there was a heavy growth of wild brush or blackberries. They are not found in cultivated fields or where the ground is bare or in well-kept parks and lawns. Usually they are absent from meadows and from weed patches unless some kind of growth of canes or shrubbery is present. They are always encountered to some extent in woodlands, but are present in great numbers only where there is a considerable growth of underbrush.

In the State of Iowa the chiggers have an even more interesting distribution. Here whole counties in the northern part of the State are apparently free from them notwithstanding that conditions for them seem ideal. The writer has collected mites for years about Ames, Iowa, and on many occasions has made special trips in search of chiggers, but has never found a single specimen in this locality. Yet the town of Ames is almost surrounded by woods and hemmed in by two creeks, and there are situations almost exactly like those along the lower Des Moines River, where chiggers are abundant.

Judging from the records up to date, chiggers are only present along the main river courses in the south-central, southeastern, and eastern parts of Iowa. From the city of Des Moines north along the Des Moines River the writer has not been able to collect specimens, although the attempt was made in several localities.

The environment found necessary in Iowa is the same as that in Virginia or Maryland, since nearly all the land is given over to cultivation; however, chiggers are found only in a relatively small area, while in the East they are found over very extensive ones.

HABITS OF UNATTACHED LARVÆ.

The belief has been almost universal that chiggers in this country are found in the grass. Observations have failed to confirm this theory. It was found that our northeastern species occurs most

exclusively at or near the surface of the soil. In this respect the larvæ differ from tick larvæ, which climb up on vegetation of various kinds and remain in wait for a host. People frequently get chiggers when they go into the grass, but our eastern species approaches from the ground. The mites can be found in surface scrapings, but repeated attempts to recover them from growing vegetation have failed.²

If chiggers attack man almost solely from the ground the question may be asked, How are we to account for attachments around the waist, under the armpits, and about the eyes? Again, observations show that chigger attacks are seldom made above the waistline, unless the clothes are quite loose around the waist, or the individual has been sitting or reclining on the ground. When one simply walks through a chigger-infested region, the larvæ are first found about the feet and ankles. Here they can be seen with a hand lens. They run with great rapidity, so fast in fact that it is very hard to catch them. From the ankles they spread upward, few as a rule attaching here, unless the clothing is tight; if so, many may attach. As they pass upward many of the larvæ either stop themselves or are stopped at the garters, if these are worn below the knees. If they pass the garters large numbers will attach in the space under the knees. Those that pass the knees usually go as far as the waistline before they attach.

Two factors are of importance in regard to the localization of chigger attachment—the tightness of the clothing at certain parts of the body and the thickness of the skin. The garters around the legs and the belt around the waist act as semi-effective barriers. For a great many minutes, sometimes for a few hours, the larvæ run over the skin hunting a favorable place of attachment. These rapidly moving larvæ are halted by the garter or belt pressure, and after struggling some time either to pass through the mesh of the clothing at these points or to extricate themselves may attach without further search. The writer has watched these active larvæ on the skin of man before and after attachment and finds that tight clothing does not aid them in "digging in" by furnishing a fulcrum, as has been supposed. In fact, it was found experimentally that chiggers do not "dig in," as has been so frequently stated, but remain attached externally like a tick does.

The thickness of the skin is of great importance in localizing chigger attachments. Where the skin is unusually thick the larvæ attach with great difficulty or not at all; and of those that do attach

² Dr. F. H. Chittenden has reported to the writer chigger attacks coming from over head vegetation. The writer has never experienced such attacks, and up to the time of the preparation of this paper none had been reported to him. It may be that a second species, which is relatively rare, occurs in this vicinity, as Dr. Chittenden suggests.

many can not remain attached during the body movements of the host or are not able to reach the lymph supply of the true skin engorge. Of the thousands of chigger attachments observed by the writer, not a single one was found on the calloused parts of hands or feet.

HOSTS.

It was the belief of earlier entomologists that chiggers lived on the juices of plants. That C. V. Riley shared this common belief is evident from the following statement (10) which he made in reference to one of his species:

The normal food * * * must, apparently, consist of the juices of plants, and the love of blood proves ruinous to those individuals who get a chance to indulge it.

When it was learned by actual rearing experiments that several species of Trombidiidae were normally parasitic on terrestrial tracheates, this older theory was dropped, and it was commonly assumed, and frequently stated, that the chigger larvæ were normally parasitic on insects and closely related invertebrates. This view was equally shared by the mite specialist and the general entomologist; but that the chigger larvæ could be normally parasitic on vertebrates was never suspected; in fact, the references to "death feast" on man or domestic animals continued as numerous as before.

When the writer began, in the summer of 1919, his search for the natural host of the species occurring in Virginia and Maryland, he collected all insects found parasitized with trombidiid larvæ. These larvæ were examined to see if any of them belonged to the species attacking man, or were in fact true chiggers. Although many insects and other tracheates were found parasitized, in no instance did these parasitic larvæ prove to be the species attacking man.

Not satisfied with this method of investigation, another was instituted. On some vacant lots that had grown up to a considerable extent in blackberries and which were very heavily infested with chiggers (over a hundred attached in less than two hours), insects of all kinds were collected. There were hundreds of them and of many species.

These insects were taken to the laboratory and examined individually, alive and after killing in cyanide bottles, and in no case was a single specimen of our eastern chigger found. The sweeping and other collections were so thorough that this observation convinced the writer that the chigger found in the vicinity of Washington was not a normal parasite on terrestrial tracheates that live above the ground.

Although never believing in the old vegetarian theory of the earlier entomologists, the writer decided to give this theory a test. First a minute examination was made of the blackberry plants, including all parts both in and above the ground. Not a single chigger was found on them. Then the examination was extended to the other plants growing on the vacant lots—goldenrod, several grasses, and a number of common weeds. Each plant species was taken by itself, specimens were pulled up, shaken over white paper, taken to the laboratory, and even examined in parts with the microscope. After several days of fruitless attempts to locate the larvæ feeding on plants the work was stopped, for evidently they could not have been feeding normally on these, or at least a few of their enormous numbers would have been encountered.

About this time there appeared in this country the extensive paper by Drs. T. Kitashima and M. Miyajima (7) entitled, "Studien ueber die Tsutsugamushi-krankheit," in which is given, among other things, a summary of the work on the life history and habits of the Japanese chigger, *Trombicula coarctata* Berlese (1). These writers claimed to have reared this chigger mite from field mice and to have established the fact that it was normally parasitic on the same. A few days later Dr. Miyajima, who happened to be visiting in this country, called at the Bureau of Entomology while in Washington. During his stay he reiterated his statement that the Japanese chigger was normally parasitic on field mice and also said he believed that it normally parasitized various other mammals.

Following the conference with Dr. Miyajima, it was decided at once to investigate the small rodents which were known to exist in the vicinity and on the ground of the infested lots. A dozen traps were procured and trapping began with these on September 13 and continued until September 24. In all, traps were set in 21 different situations, including 13 in the infested area and 8 on adjoining unfested ground. Small mammals, chiefly rodents, were caught and examined microscopically in the laboratory as follows:

September 13-----	4	September 18-----	2	September 23-----	1
September 15-----	3	September 19-----	1	September 24-----	1
September 16-----	1	September 20-----	1		
September 17-----	2	September 22-----	1		

In all, 17 small mammals were caught, all within 11 days. Among those obtained the following were determined by Dr. Ned Dearborn, of the Bureau of Biological Survey: House mouse (*Mus musculus*); common meadow mouse (*Microtus pennsylvanicus*); short-tailed shrew (*Blarina brevicauda*).

Not only were the skins of these mammals examined carefully, but the ears and some of the other parts were removed and washed violently in alcohol and the washings examined. As a result of these examinations not a single chigger was found.

This examination of the small mammals of the infested area, it should be noted, was made late in the season. It is possible that if the trapping had been done earlier, different results would have been obtained. During the summer of 1921 such trappings are planned for the months of June and July. It will be interesting to observe the results.

Among other hosts held under suspicion were reptiles. Tortoises were found in the vicinity of the infested area. These were caught and examined, but no chigger larvæ were found. Early in July, 1920, Mr. William Palmer, of the National Museum, captured a large king snake, *Lampropeltis getulus getulus*, at Chesapeake Beach, Md., that had hundreds of mite larvæ attached to its skin, between the scales. He brought the snake to the Museum, and when it was shown to the writer a few days later it had molted. In the cast skin were found hundreds of trombidid larvæ in various stages of engorgement. An examination of these showed them to be no other than the chigger that attacks man along the Atlantic slope. Parts of the cast skin with chiggers attached were placed in breeding cells, and chiggers that appeared fully engorged were likewise placed in breeding cells, but in neither case did any of the larvæ transform into nymphs.

Those attached to the skin of the snake remained attached and soon died unless forcibly removed. The actions of the chiggers in remaining attached to the skin after the latter was cast and their dying in this attached position would seem to show that the king snake is not a natural host. Further, it is known that chiggers exist in enormous numbers where very few snakes of any kind are found.

The determination of the natural hosts of our American chiggers has not been made. Further investigation along this line is needed.

INJURY.

CHIGGER INJURY CONFUSED WITH MANY OTHER KINDS OF INJURY.

Of the many complaints about chiggers that have come to the writer, a very large number, fully one-half in certain sections, were found upon investigation to be due to hives, caused by the disagreement of some food eaten and probably accentuated by hot weather. A very large number of complaints supposed to be concerning chigger attacks were found to be due to nettling from some thorned plant. Serious attacks in a front lawn in Virginia, reported to be



FIG. 2.—Right chelicera of a chigger-mite larva from the inside, X 1,200. Drawing made from specimen taken at Lake Minnetonka, Minn., and belonging to the University of Minnesota collection.

due to chiggers, were found to be due to *Trisetastes missouriensis* Ewing, a gamasid mite, the habits of which are not well known.

Injury from fleas is very similar to the first-stage injury of chiggers, and since fleas soon leave their hosts and chiggers are so small that they frequently are overlooked, flea injury is mistaken for chigger injury. A careful examination with a hand lens will enable one to see the attached chiggers and prevent confusion of flea injury with an attack by chiggers.

DO CHIGGERS PENETRATE THE SKIN?

Both among entomologists and the public generally there is a belief that chiggers burrow into the skin. C. V. Riley (10) states in regard to his *irritans* that "This mite is able to bury itself completely in the flesh." In speaking of the same chigger, Osborn (8, p. 252) says: "It is brushed from the leaves of various plants onto the hands or clothing of people and to the bodies of other animals, and the mite then proceeds to burrow into the skin."

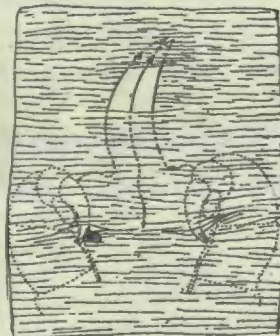


FIG. 3.—View showing the method of attachment of a chigger (northeastern species). Drawing of a part of a "slice" of skin, made from the underside while the larva was attached.

To find out whether chiggers penetrate the skin or not, and also to observe their injury, resort was made to experimentation. On July 15, 1919, the writer exposed the left calf and ankle to chigger attack, and after the mites had settled numbered 10 individuals by writing on the flesh near the mite with ink. Daily observations were made on these chiggers, using low and high

power lenses, for the next eight days. It was observed on the first day that the mites attached only by their mouthparts and in no way burrowed into the skin. Observations on the second day showed no change; in fact, after once attaching to the skin by their mouthparts the larvæ became quiescent and did not change their position until they dropped off. By means of a razor blade several individuals were removed by slicing off a small area of the epidermis around them. When this "slice" of epidermis was examined under a high-power microscope objective it showed the attachment as represented in figure 3. The hooked and ventrally barbed chelicerae were thrust into the epidermis only, and the palpal claws were found forced downward and backward into the epidermis. After both the chelicerae and the palpi have been inserted in this fashion they hold the larva locked, as it were, to the skin. This was made evident by watch-

ing the actions of larvæ with high-power objectives after they had been removed with a "slice" of epidermis. They wriggled first one way, then another, pulled with all their strength backward and forward, gave side twists, and in fact strained in almost every possible way until released. One individual was timed during this process, and it took it seven minutes to free itself from the hold it had obtained on the epidermis.

These observations were repeated upon a lot of 16 individuals for nine successive days. They were numbered as before, and daily observations made upon them. Not only did none of these larvæ burrow into the skin, but they remained attached only by their mouthparts and engorged like ticks. Later they released this hold and fell off.

DO CHIGGERS ENTER THE PORES OF THE SKIN?

Some authorities, while not believing that chiggers burrow into the skin, yet hold that because of their minute size they enter the pores and thereby cause much inflammation and other injury. This point has been carefully investigated. Of the 26 numbered individuals that were observed and studied daily, 21 were attached to the smooth surface of the skin, while 5 were attached at the bases of hairs, each having the capitulum thrust into the mouth of the hair follicle as shown in figure 4. Not a single one had penetrated a pore or hair follicle.

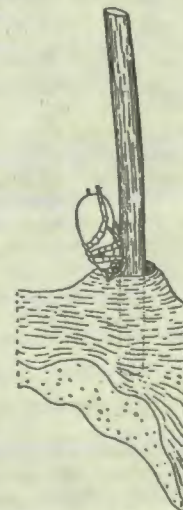


FIG. 4.—"Slice" of epidermis from the skin of calf of leg showing method of attachment of eastern chigger in mouth of hair follicle.

The species occurring in the northeastern part of the United States shows a tendency to attach at the mouth of hair follicles. It may be that the larvæ actually try to enter. They are prevented, however, from doing so under normal conditions of the skin by the small diameter of the follicles themselves. For this same reason it would be impossible for chiggers to enter the pores of the skin, unless the latter were greatly dilated as a result of some skin trouble. In diameter the pores of the skin range from 20 to 50 μ , according to Piersol. The width of an unengorged larva from either the western or eastern part of this country is approximately 150 μ . Thus it is seen that unless the pores were unusually dilated the mites could not enter if they would.

In the case of persons who have just cleaned out the pores of the skin after a long period of negligence, it would be possible for the mites to enter some of them, as, for example, pores dilated by comedones. The writer has observed such pores dilated until they were

fully 400 or 500 μ in diameter. These pores, however, are most frequently on the face or neck—regions seldom attacked by chiggers. In all the observations made, including many hundred, of chigger attacks, it has always been possible during the early stage of attack to locate the chiggers themselves or their evident places of attachment, and this has always been on the surface of the skin or in the mouths of hair follicles.

DIFFERENCE IN SUSCEPTIBILITY.

Another common belief among the public and entomologists is that a great difference exists between persons in susceptibility to chigger attacks. Such a difference usually has been assumed to be physiological. Observations were made to ascertain the foundation for such a belief, if any existed. Upon several occasions it was observed that there was a difference in injury to people who apparently had all been exposed equally to the attacks of chiggers. It was found in most cases, however, that although all members went on the same picnic, or collected berries in the same patch, or made the same journey, they were not equally exposed to the attacks of the mites. Particularly three fundamental differences were found: First, a great variation in the clothing, especially about the feet and ankles; second, a variation in the actions of the persons, some never sitting or reclining on the ground; and third, a great variation in the intensity of chigger infestation even over a small area. Observations clearly show that these are usually the reasons why some members of a party are but slightly attacked while others are driven almost frantic.

Laboratory tests show that chiggers attack by preference where the skin is very thin and the flesh wrinkled or tender. Field observations also have brought out the fact that women and children suffer more from a given number of chiggers than men do. In other words, a correlation exists between thin skins and seriousness of chigger attacks. This, however, is the only way in which certain differences in the seriousness of chigger attacks between individuals equally exposed could be explained. Although hundreds of people were found susceptible to chigger attacks, no one was found who was clearly shown to be immune.

LOCAL INJURY.

Since there has been so much confusion in regard to chigger injury, a careful tabulation was made daily in the case of two lots of infestations. The first lot of 10 individuals, located on various parts of the leg below the knee, were numbered and notes made daily upon the appearance of the local area around each point of attachment, with the following results:

Attachment of chiggers followed irregularly within a few hours after exposure. The itching which appeared during the latter part of the first 24 hours following attachment grew in intensity. At 48 hours after attachment not a single papule had appeared at any of the 10 points of attachment. During the second day swelling subsided, and the pinkish coloration around the puncture points was followed, first by a light blood-red and later by a deep blood-red color. The immediate area around each larva changed to a whitish color, and the discolored area as a whole was large and in some cases mottled with light and dark red. The itching sensation reached maximum the second day.

During the third day after infestation most of the spots changed from the pinkish or light blood red of the second day to a deep blood-red or purplish red. At the end of the third day one-half the larvae had become detached.

During the fourth day few changes were noticed. One more larva had dropped off, and a few of the spots were observed to be lighter in color than the day before.

During the fifth day all the remaining larvae dropped off. Spots retained most of their color and in four instances small water blisters developed near the center of discolored spots.

On the sixth day the color of the spots continued to fade and in one instance was practically lost.

During the seventh day several of the spots regained almost the normal flesh color. Five water blisters were observed, but only one was conspicuous.

On the eighth day the discoloration had entirely disappeared in one instance and almost so in two others. Two water blisters were left.³

GENERAL DISTURBANCES.

As has been known for many years, general disturbances frequently follow serious attacks from chiggers. Among the most serious of these is the development of a fever and a temporary upsetting of certain nervous responses. Oudemans has recently called attention (11, p. 10) to the narrative of Alfred Russel Wallace relative to the latter's experience with chiggers in the Malay Archipelago. This eminent naturalist wrote:

All the time I had been in Ceram I had suffered much from the irritating bites of an invisible acarid, which is worse than mosquitoes, ants, and every other pest, because it is impossible to guard against them. This last journey in the forest left me covered from head to foot with inflamed lumps, which after my return to Amboyna, produced a serious disease, confining me to my house for nearly two months * * *.

³ The appearance of these water blisters is well illustrated by Riley and Johann (11, fig. 43).

In this country Prof. Herrick (4, p. 317-325) has made observations on chiggers in various parts of the United States. He says:

Very often a slight fever accompanies the eruptions and the patient is liable to lose sleep and suffer almost unbearable torture.

In regard to the general disturbances caused chickens the same authority states (5, p. 258-260):

The chicks seem to contract a diarrhea, grow weaker and weaker, and finally die.

Where the attacks from chiggers are slight, as a rule, no general symptoms are produced. When there is a sudden attachment of several hundred larvæ general symptoms may result. The irritation produced by such a large number may prevent sleep for several nights in succession and thereby upset or disturb digestion. Also, a peculiar nervous disturbance may be caused. This may be brought about by toxins injected by the larvæ or by some other cause.

During the months of July, August, and September, 1919, the writer on many occasions was attacked by chiggers. Some of these attacks were severe and on more than one occasion blood-red spots larger than a half dollar were left. As a result of these repeated attacks a peculiar nervous effect was produced. During parts of the day a feeling of lethargy was noticed, yet to many things a hypersensitiveness was produced. This irritable state became so pronounced at times as to make productive work all but impossible. With this upsetting of the nerves, interference of bodily processes was observed to a considerable extent. It was only after the cool days of November that a normal condition was restored.

RELATION TO DISEASE.

Until the work was begun in Japan on the cause of flood or river fever ("tsutsugamushi-krankheit") some 15 years ago, chiggers had enjoyed an almost complete freedom from suspicion as actual disease carriers. As the work on this deadly disease progressed, however, they were soon held to be implicated in some way and finally shown to be the active carriers of the virus of this disease.

The results of various Japanese workers show that this disease is caused by a nonfilterable virus which is transmitted by means of the chigger bites to man. The natural reservoir is apparently the normal hosts of the chiggers, chiefly field mice, as only a small percentage of the larvæ are infected. Kitashima and Miyajima (7, p. 232) state that while "tsutsugamushi-krankheit" is similar to typhus fever and Rocky Mountain spotted fever in that the virus is nonfilterable and arthropod-borne, yet the disease itself is quite different from either.

River fever is a very deadly disease, as about one-third of all the cases are fatal. The only regions of the country affected are those along the water courses or in lowlands. Various attempts have been

made to discover and work out the development of the causative organism, but to no avail.

Among the various substances that have been employed in medication in connection with the disease the following have been used with negative results: Quinine, iodine, quicksilver, arsenics, and staining preparations. From the beginning to the subsidence of the fever salvarsan and trypan red have been used with very poor results. An attempt has been made experimentally to utilize a serum for the disease, but without results.

As chiggers are parasitic only in their larva stage and do not change hosts, it appears that the causative organisms must be transmitted from larva to nymph, to adult, thence to egg and to larva again. Such a development, although a little unusual, already has a near parallel in the case of the protozoan *Piroplasma bigeminum*, the organism of Texas fever, which is transmitted from mother to egg to larva or to nymph, in its alternate host, the North American fever tick, *Margaropus annulatus* Say.

In view of what is already known in regard to the transmission of river fever, the biology of the chigger mites, and the general symptoms following their serious attacks on man and domestic animals, the writer now predicts that in the next 50 years other serious diseases will be shown to be transmitted by these acarids. Should these mites become the transmitters of fatal diseases of domestic animals on a large scale it would be found that the protection of cattle or sheep from them would present a very difficult problem, as the mites are so minute and so widely distributed in woodlands and along water courses.

CONTROL.

In the case of man much protection can be had from chigger attacks by properly clothing the lower extremities or by the application of repellents either directly on the skin or on the under garments.

PROTECTION AGAINST CHIGGER ATTACK.

Since the unengorged larvæ are not over 150µ in width, it is seen that they can pass through the mesh of many kinds of garments; it is easy, however, to wear those of a weave tight enough to prohibit the larvæ from passing directly through the cloth. The employment of tightly woven cloth, or other materials which are impervious to the larvæ, nevertheless, is not enough. These garments must be worn so as to fit tightly around the edges or the larvæ will yet have an avenue of entry.

It was frequently noticed that half-shoes exposed the ankles, and for that matter indirectly the whole body, to much more serious

*The control of chiggers affecting poultry is considered in Farmers' Bulletin 801. The measures given in the present bulletin have reference more particularly to chiggers as parasites of man.

attacks than topped shoes. This the writer demonstrated himself many times. High-top shoes or, better yet, laced boots, gave a considerable amount of protection. On several occasions the writer was accompanied on his trips by Mr. W. W. Diehl, of the Bureau of Plant Industry. Mr. Diehl demonstrated well how the body could be protected by wearing topped shoes and spiral puttees. The latter were wrapped tightly about the calves and gave almost complete protection.

Concerning this method, however, there are two objections: First, it causes a considerable discomfort to wear such tight and rather heavy clothing during the hot season, and second, if the individual sits down, reclines, or brings the hands in frequent contact with the surface of the ground, the chiggers will attack in considerable numbers.

Another method of gaining protection which has been tried in the past is to use some repellent on the skin or on the clothing. Sulphur has long been recommended for this purpose and Dr. Chittenden (2, p. 5) calls it "a sovereign remedy for mites." A test of its efficacy was made as follows:

At East Falls Church, Va., on July 25, 1919, before going into a well-known infested area, the left stocking and the lower part of the underwear on the left leg were dusted inside and out with flowers of sulphur. The sulphur was applied by the "pinch method," followed by rubbing. About a tablespoonful was used. From 2.30 p. m. to 4.20 p. m. there was exposure to attack in the infested area, and at the end of this time a laboratory examination was made. On the calf and ankle of the untreated leg several chiggers were observed, all unattached and running about very energetically. On the calf and ankle of the sulphured leg not a single chigger was found. Later, at 9.45 p. m., another examination was made. The untreated leg had a large number of chiggers attached, these being distributed from the ankle to the hip. The treated leg did not have a single chigger attached.

On August 4, 1919, a test was made to see if a dusting of sulphur on both sides of the clothing was any more efficacious than dusting on one side only. The stocking and underwear below the knee on the left leg were sulphured by the "pinch method," both inside and out. The stocking and underwear below the knee on the right side were sulphured as before, but only on the outside.

At 3.30 p. m., after exposure, an examination of both legs failed to reveal a single chigger. It was noticed also that there was much more sulphur adhering to the left leg than to the right. A later examination at 11.30 a. m. the next day failed to reveal a single chigger on the left leg and only one chigger wheel on the right, this being near the instep of the foot.

It would appear from this that the dusting with sulphur inside the hosiery and underwear is sufficient if it is so applied as to be well distributed. Later tests fully demonstrated that a single application was sufficient if well distributed.

The "pinch method," i. e., applying a powder insecticide by picking up small amounts with the thumb and fore finger, while well adapted for dusting lousy chickens, for example, was observed to be both tedious and wasteful, hence other methods were resorted to.

Application by means of a talcum shaker was made on August 9, 1919, followed by exposure at Vienna, Va. Examination that night showed it to be 100 per cent effective.

On August 15, 1920, application was made with a pepper shaker. A considerable tendency of the sulphur to clog the small holes of the top was noticed, but by violent agitation a fairly even application was made. Only the inside of the stockings and the lower part of the underwear were treated. Exposure for about 3 hours was made in the woods north of Chesapeake Beach, Md. Later examination showed 100 per cent efficiency. It should be added that if sulphur is dusted by means of a salt or pepper shaker, after the operation all unused sulphur should be removed and the container washed. This will prevent the tarnishing of the metal parts of the shaker.

Mr. Flint, of the State Natural History Survey of Illinois, states that he has applied sulphur by means of a small bag and also by the "pinch method," with good results. Dr. J. W. Folsom also reports good results from sulphur treatment by the "pinch method." During the summers of both 1919 and 1920 several members of the bureau staff tried the use of sulphur, and in every case good results were reported and usually complete protection.

DESTRUCTION OF BREEDING PLACES.

It is hoped that the observations made on the habits and local distribution will enable much more to be done to advantage in destroying the breeding places of chiggers. Especially is this method of attack to be recommended about private dwellings and in poorly kept public parks and at summer resorts. Already its feasibility has been demonstrated. In and around Washington many chigger-infested lots or fields have been automatically rendered free of chiggers by turning these to cultivation or cleaning away the rough growth. Prof. F. L. Washburn (12) has the following to say in regard to the effect of cutting down bushy growth in Minnesota:

Capt. Zimmerman, living on Enchantment Island, Lake Minnetonka, having found this pest troublesome on his own island and upon the neighboring Phelp Island, has reduced their numbers materially by cutting out much underbrush thus letting in the sunlight.

A well-known golf course was laid out west of the District of Columbia in a region heavily infested with chiggers. Later an investigation showed that the sodded areas where the balls were played were quite free from chiggers. When persons went into the patches of rough growth between or around these areas they were attacked by chiggers.

A chigger-infested lot in East Falls Church, Va., was cleared of rough growth and a house put on it during the summer of 1919. These operations destroyed the breeding places of the chiggers.

Of all the growths that favor the harboring of chiggers none is more favorable than wild blackberries or wild dewberries. Wild blackberry patches in Virginia and Maryland invariably were found to harbor immense numbers of chiggers. Where such patches are located at very objectionable places their obliteration would seem justified. The fruit produced by these wild canes is of a good quality, however, and constitutes not a small item in the summer food supply of the country; hence a wholesale destruction of wild blackberries would be both rash and foolish.

Dr. Chittenden has mentioned (2) the value of cattle and even of the passing of many persons in destroying chiggers. In 1914 (3) he published the results of a conversation which he had with Mr. William N. Irwin (through an error given as E. F. Erwin), who before his death was connected with the Department of Agriculture; in this conversation Mr. Irwin stated that he considered cattle inadequate where a large area was to be dealt with. He claimed, however, that he had experienced good results where sheep were used instead of cattle. The efficacy of sheep in chigger eradication thus being shown, an explanation of their agency and its effect on the chiggers is due. Dr. Chittenden claimed that the value of cattle in chigger control came from the trampling of the pests, and he would explain in the same way the benefits from the utilization of sheep, adding, however, that the sheep are probably more effective, by "keeping the grass more tightly cut than would cattle." Mr. Irwin explained the agency of the sheep as being due in part to the ascent of their legs by the chiggers and their destruction through contact with the oil in their wool. The present writer would explain this observed difference between the efficacy of cattle and sheep as being due chiefly to the food habits of the latter, the sheep not only keeping the grass more closely cropped, but also feeding to a considerable extent on the leaves of shrubbery.

Just what the value of a certain amount of shrubbery is to chiggers is not known in the case of our species. It may furnish a favorable environment for the natural hosts of the parasites, or furnish the necessary environment for either the nymphs or adults of the chiggers, or both these instars, or furnish a proper environment for the larvæ.

It has been stated that the cropping or mowing of grass lets more sunshine and in this manner destroys the chiggers. This, hardly be the case, however, as larvæ have been handled and exposed frequently in the bright sunshine and no ill effects to them noted. In the field also, where there is only a scant growth of dewberries, an abundance of sunshine chiggers may be found in great numbers.

Chiggers are almost semiaquatic and will endure frequent emergence. In the laboratory they do well, if not their best, in atmosphere near saturation. This humidity requirement will explain the advantage of a rough growth to the species, which live almost exclusively at the surface of the ground. In most situations it may be that the moisture is only sufficient when the ground is clothed with a considerable growth of vegetation. Thus the effect of sunshine would appear to be indirect and to destroy the chiggers in most situations where allowed to act by drying the surface of the ground.

DESTRUCTION OF THE CHIGGERS THEMSELVES.

It is stated that chiggers may be destroyed by a liberal application of sulphur to the field. The use of 50 pounds to the acre has been recommended. For this purpose a dust gun or dust blower could be used to advantage. On lawns the use of sulphur is unnecessary, as chiggers will automatically disappear if the grass is kept cut short.

Chiggers may best be destroyed on the body of man before they become attached or very soon afterwards. If one knows that there has been exposure to chigger attacks the shins and ankles should be examined with a hand lens for the active larvæ even before any itching sensation is felt. Only a few of the active larvæ will be observed. They will be seen to run over the skin very rapidly and can not be captured to advantage.

Larvæ on the body can be easily killed by the application of an acaricide. Various substances applied at the time of bathing have been recommended. On August 10, 1919, after exposure to chigger attacks, a thick lather of soap was applied to the affected parts. The lather was allowed to remain for 10 minutes and was worked continually over the skin. After 10 minutes it was washed off. Examination next day failed to reveal any chiggers and no itching developed.

On August 18, 1919, after exposure at Somerset, Md., and where larvæ had attached, the same application of thick soap lather was tried. On the 19th much itching was felt, yet no chiggers were found. Apparently the soap had acted as an acaricide but not as a palliative.

Dr. Maurice C. Hall, of the Bureau of Animal Industry, reports excellent results from the use of sulphur ointment against the larvæ after they have become attached.

Commercial alcohol (95 per cent) has been used by several acquaintances and by the writer himself to good advantage against the chiggers attached to the skin. When the free larvæ are immersed in alcohol and observed under the microscope they are seen to die in short order, usually in from 1 to 3 minutes. The alcohol is an excellent acaricide and also a good antiseptic for the unabraded or slightly abraded skin, and has a further advantageous effect in hardening the dermis. It should be applied quite freely and the application repeated two or three times.

Any of the lighter oils kill the larvæ quite rapidly, and can be used to advantage against the larvæ if the latter are confined to a small area on the body. Sulphur acts slowly, but if applied with soap and allowed several minutes to act should give good results.

PALLIATIVES.

To those who go little afield and are thus ignorant of some of nature's ways warnings that preventive measures should be taken are usually but little heeded, hence it is necessary to give directions in the use of palliatives—the most unsatisfactory of all measures. Undoubtedly most of the so-called palliatives are of value chiefly, if not entirely, because of their acaricide action or because they act antiseptically, or in both these manners.

In the Panama Canal Zone, according to Dr. W. A. Taylor, Chief of the Bureau of Plant Industry, a saturated solution of salicylic acid in alcohol, with a little olive oil added, has been used to good advantage as a palliative. Both he and Mr. H. H. Bennett, of the Bureau of Soils, used this mixture with very beneficial results in the Canal Zone.

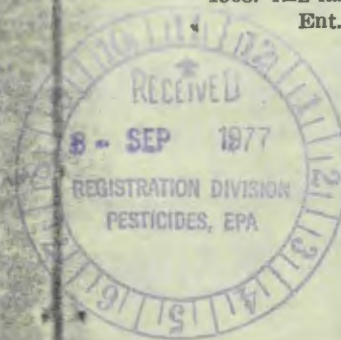
In the Southern States, according to Mr. Bennett, butter or lard with a liberal mixture of table salt, or pure kerosene oil, is frequently used as a palliative. With regard to their benefit he says: "I am still not convinced that they are more than moderately efficacious * * *."

Among the other substances recommended as palliatives are the following: Ammonia, cooking soda, dilute solution of iodine, camphor, and alcohol. Statements made to the effect that an acid toxin is injected by the larvæ are not based on observed fact or experimental demonstration. We do not know even that a toxin is injected by these acarids. As before stated, the intelligent use of palliatives awaits experimentation on the nature of chigger injury from the physiological standpoint.

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tensive examination is indicated. It is believed that a follow-up with a much larger number of cases and with a possible refinement in the list of questions would ultimately result in an objective measure for determining the mental capacity of the illiterate registrant that would be an aid to the interviewer.

It may be well to note that the number of malingerers found during the examination was negligible and does not appear in the tables. Such cases were easily identified because of the manner in which they answered questions. Any individual who answers questions 1, 2, and 3 in a negative manner and then unhesitatingly answers question 4 and either 5 or 6 correctly, gives evidence of malingering.

This study is not offered as a panacea afforded the neuro-psychiatrist who, in examining registrants, must differentiate the illiterate non-defective from the illiterate defective, and both of these from the poorly educated indi-

vidual who thinks that failing to operate in a literacy test may be an easy way to postpone or even avoid undesired service in the army. Although we have too few cases to draw scientific conclusions, the trend indicated by the study is important and the study itself is sufficiently timely to warrant attention to the basic matter which is simply an endeavor to formulate a very short objective test of intelligence pointed toward the ten-year level. This mental age level was chosen since, at the time of testing, it was used as the minimum level for acceptance of men for service in the army of the United States.

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Fort Barrancas, Fla.

A DISCUSSION OF THE CHIGOE (*TUNGA PENETRANS*) BASED ON EXPERIENCES IN BRITISH GUIANA*

By MAJOR CHARLES O. BRUCE, *Medical Corps, U. S. Army*, TAMARATH
D. KNIGIN, AND STANLEY F. VOLLES

(With seven illustrations)

ALTHOUGH the human flea, the dog, cat, and rat fleas are well known to medical science because of their public health significance, another flea, which in habit is more truly a

parasite of man than the common human flea, remains confused in the literature, misnamed, and its habits erroneously described. This flea, variously known as the "sand flea," "chigoe," "chigger," "jigger," "nigua," "chique," "djigga," etc., is known scientifically as

* From the Engineer Hospital, British Guiana Base.

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Tunga penetrans. In the older works this same flea was described under a variety of generic names such as *Pulex* Linnaeus 1758, *Dermatophyllus* Lucas 1839, and *Sarcopsylla* Westwood 1840. It was taken out of the genus *Pulex*, in fact, out of the family *Pulicidae*, on morphological grounds and on the basis of priority the name *Tunga penetrans* is valid since it was figured under that name by Jarocki in 1838.

It is unfortunate that some of the common names used for this form resemble closely or are identical with the common names of other parasites. Writers using terms loosely often interchange "sand flea" and "sand fly" with the result that the reader does not know if the flea is intended or *Phlebotomus*, the sand fly. More important is the confusion existing between the name, *Trombidium irritans* ("red bug" or "bete rouge"), and *Tunga*. Both forms share the common names "jigger" and "chigger." To avoid this confusion it would be best to restrict the names "chigger" and "jigger" to the mite, leaving "chigoe" which has never been used for the mite as the common name for the flea (Fig. 1).

People in infested regions tell what would seem to the uninitiated to be fantastic stories of the nuisance value of this pest. We, because of our own experiences, realize that these stories are within the realm of truth. Within weeks after arriving in British Guiana one of the authors had thirty chigoes removed from both feet. As many as seventy-two have been removed at one time from one of the patients in the hospital. This in a camp



FIG. 1. *Tunga penetrans*. Female chigoe before entering skin ($\times 32$).

which had already been cleared and graded!

Richard Schomburgk travelling in the interior of British Guiana in the 1840's wrote the following account of the chigoe conditions he found in a Warrau Indian village:

"Besides affecting certain of the adults, a no less pitiful appearance presented itself amongst a number of children in particular, whose feet and buttocks were covered with awful boils as a result of which the extremities in some of the cases were deformed into real club-foot. Upon inquiring into the cause of the disfigurement I learnt that the sores were due to chigoes, a small species of flea, *Pulex penetrans*, which very generally at night digs itself under the nails and skin of the foot. . . . From the fact of these pests choosing not only the foot but also the breech the greatest number of the Warrau youngsters bear mournful testimony of their parents' neglect and dilatoriness. . . . For some time past I had experienced at night a continual itching and burning sensation, especially in the toes and under the soles

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flap contains the entire insect. A clean, glistening, pit sometimes of alarmingly unsuspected depth remains. It is touched with an antiseptic and dressed. Complete healing occurs in a few days. In treating over 3,000 cases of chigoes at this hospital, there has not been one

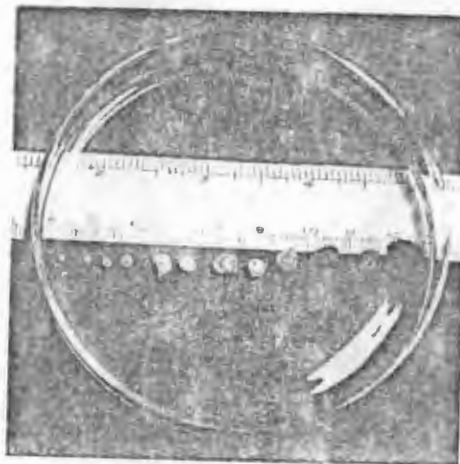


FIG. 7. Excised chigoes showing variations in size.

infection when this technic was used.

The use of lotions, ointments, creams, and dusting powders for the treatment of chigoes is not recommended.

PREVENTION

Chigoes are not known to be vectors of disease, but feet that are pitted by chigoe ulcers are not good marching feet, and troops who flock to sick-call to have chigoes removed or their ulcers

dressed are losing valuable time. Furthermore, the temptation to remove one's own chigoes is great and often leads to infections and time spent in hospital bed. Therefore, camp sites should not be chosen in localities known to be inhabited by *Tunga penetrans*. If such a selection is unavoidable, the Sanitation Officer may institute a program such as the following:

1. Educational talks are given to stress the danger of self-treatment.
2. The men are urged to wear high-top shoes out-of-doors, and to avoid going bare-footed inside their barracks.
3. Floors are mopped daily and treated with an antiseptic solution.
4. Precipitated sulfur is incorporated with the foot powder and dusted on the feet every morning.

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of the feet, but paid no attention to it hitherto, as I generally started on my outings directly at daybreak: it soon increased however to such an extent one evening that I got a coloured man to examine my foot next morning and was not a little surprised when he assured me that a whole mass of sand fleas were buried in the parts affected. I immediately had to submit to the painful operation of having 83 specimens extracted within the course of half an hour, and I still call to mind with a cold shudder those minutes when at last, on the soles being cleared, the nails had to be cut to pieces in the spots where the insects had settled. The orthodox Indian practice is to take a pin or needle, pick away and turn aside the superficial and surrounding skin and then squeeze out the capsule in its entirety. The burrowing of the vermin is not taken notice of at all, because a slight itching, with which it commences its burrowing, cannot disturb ones deep sleep after a strenuous day. It is only after the first 48 hours that marked inflammation is set up, when one finds in the painful places a bluish spot about the size of a pea. So long as I yet remained free from the plague, I had often had to smile at the gruesome grimaces noticeable each morning when, on interrupting my outing, I went over to the Indians' houses where the whole adult family, squatting around on the ground would be examining their feet from all points of view to see whether the sharply pointed little pieces of wood or the knife was required. Even the poor dogs were plagued most unmercifully with chigoes, which also in their case bury themselves in the sole and make it practically impossible for the animals to run. . . . The miserable, yelping, whining, and whimpering beasts can generally be seen tearing and biting away at their paws. . . .

"The adage: 'Experience bought is best' found me an apt pupil, for from now onwards I never missed having my feet examined every morning and on few occa-

sions did it happen that 20 to 30 were extracted, this finally reducing the annoyance of my nails and all things to practically nothing."

Even the folklore of the Indians has been influenced by the plague. A story is told that one of the great waterfalls in the Colony of Ontario, Niagara—was named for an Indian whose great-grandfather became so tired of taking his feet every day that he got into a canoe and sent him to the pest.

"I'll be jiggered," Chigoes is an old sailor's oath that has its origin in some seaman's experience with the pest.

Brazil is considered to be the home of this flea. From there it has spread to tropical America and the West Indies, between 30° N. and 30° S. In 1872 it appeared in Africa and adjacent Asia. It seems to be in the path of the monsoon. In recent years it has been reported from Karachi, India where it was introduced by Indian soldiers who had been working on the railways in Africa.

Although there is no evidence that *Tunga penetrans* has been introduced in the United States, the southern states are well known to harbor the insect. Wherever troops spread throughout the country there is the very strong possibility that the chigoe might be brought in. In the dry, sandy, semidesert regions of the United States it has been established there.

The sand flea is the most common

The males and unimpregnated females are about one millimeter long and are from *Pulex irritans* by having a more rounded head. Chigoes are usually red or a reddish brown. Their legs have ranged to dark brown and even to black. . . .

Chigoes live in dry, sandy localities, usually near human habitation, but it is possible that they may be found in places where humans never lived. Native villages have become so heavily infested with chigoes that the whole population was forced to move elsewhere. Chigoes feed on most warm-blooded animals, but are especially attracted to humans. In its life cycle *Tunga penetrans* is more parasitic than other fleas. All chigoes feed intermittently on the host throughout the adult life, usually during its close association with but not on the host. The human flea lives in the burrows of men, and the rat flea is found to eat burrows or nests, jumping from the host at will. One of the most common memories seeing a sand cliff filled by nests of bank swallows whose entrances look like small holes. When an object is dropped into the nest it would be covered with fleas; when it was withdrawn the fleas would all jump out. This illustrates the transient relationship of the fleas to the birds.

The situation is different with *Tunga penetrans*. Males and unimpregnated females feed intermittently as do other fleas. When the female is fertilized she burrows into the skin of her next victim and remains there for the last two segments of her life.

of her body to plug up the entrance hole. The favorite sites of attack in man are the soles of the feet and under the toe-nails, although other parts may be affected (Fig. 2).

The epidermis is penetrated to a



FIG. 2. Chigoes on buttocks and lower extremities. This native had 126 chigoes distributed over his body.

depth of about one millimeter by the fecund female. Spines directed posteriorly prevent her from falling out or being extracted. As she feeds on the host's body fluids maturation of the eggs proceeds, and the abdomen swells to many times its original size, growing to about nine millimeters in diameter. With this increase in size the head of the flea extends farther into the host, finally reaching the subcutaneous fatty tissue (Fig. 3). A raised area on the surface of the skin forms at this time. The mature female contains at least 100 eggs, each about 400μ long.

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the abdomen at the surface of the skin and drop to the ground where, after

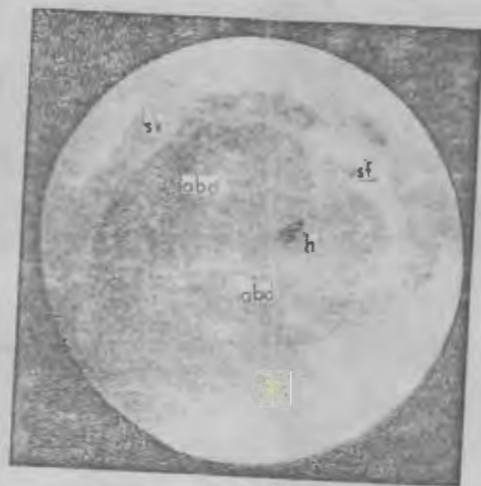


FIG. 3. Chigoe after extraction from toe. h, head, the part of deepest penetration; abd, abdomen filled with maturing eggs; sk, skin of the toe; sf, subcutaneous fat. (X10).

three or four days, the larvae emerge. Successive molts are followed by pupation, and the imagoes or adults emerge about 28 days after the eggs have been deposited.

As the female flea enters the skin of man very slight to moderate itching is produced, depending upon the site involved and the mental preoccupation of the host. On the feet, the burrowing process may go unnoticed but on the penis or finger there may be enough itching to cause the individual to investigate and discover the flea. It takes the insect about four hours to penetrate to a satisfactory depth in the skin.

During the first few days of parasitism symptoms are absent or slight. They are noticed when the enlarging body of the flea reaches sufficient size

to cause irritation. The amount of distress is quite variable. In some cases there are no symptoms until the insect is accidentally discovered while the patient bathes or dresses. In other cases the irritation is so severe that the patient is unable to rest in the middle of the night. The lesion is rarely present, but may be caused by pressure on the area of infestation.

The lesion on the surface of the skin can be seen easily after the insect has developed. There is a small, circular, yellow area a few millimeters in diameter, with a central dark spot. The skin around the area is usually inflamed. The dark spot is the terminal portion of the flea's abdomen, showing the rest of her abdomen is protruding from the sac of eggs, showing the rest of her abdomen is protruding from the thinned out cornium as the flea enters.



FIG. 4. Head and thorax of chigoe under high magnification.

cle mentioned above of that has been in the skin for a measure four millimeters. Variations in size from

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FIG. 5. Two chigoes in situ.

mentioned authors who have discussed the frequency of chigoe infestation. Variations in size from

TREATMENT

The treatment of chigoe infestation is surgical removal of the insect. This

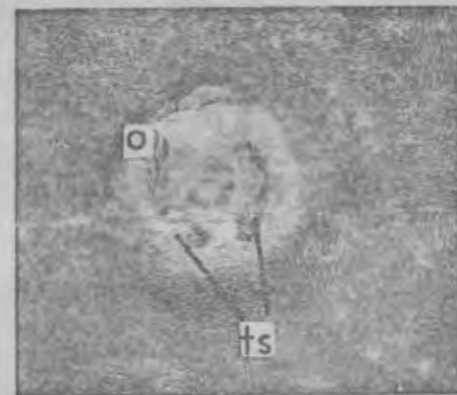


FIG. 6. Skin of toe magnified to show the opening made by the flea. ts, terminal segment of flea; o, opening through the skin.

may mean simply plucking out the flea as she enters the skin, or, later, as is usually the case, may involve dissecting out the enlarged gravid female. The object is to remove the entire flea, including the unruptured, swollen abdomen and the minute head which is deep in the skin.

The site is painted with an antiseptic solution. An anaesthetic is not necessary. A sterile sharp scalpel, preferably a Bard-Parker #11 blade, is introduced at the outer edge of the lesion, at its junction with the inflamed skin. An incision one millimeter deep is made and carried around two-thirds of the circumference of the area. Care should be taken not to rupture the distended abdomen. The cut skin is then grasped with thumb forceps, a flap reflected by blunt dissection and severed at its base with scissors. The reflected



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infested it may be necessary to thoroughly scrub the floors with hot soapsuds, or to spray them with gasoline. If the latter method is adopted, care must be taken to avoid the possibility of fire.

To clear a house of fleas Skinner recommends the use of flake naphthalene. In a badly infested house he took one room at a time, scattering on the floor five pounds of flake naphthalene, and closed it for twenty-four hours. It proved to be a perfect and effectual remedy and very inexpensive, as the naphthalene could be swept up and transferred to other rooms. Dr. Skinner adds, "so far as I am concerned, the flea question is solved and if I have further trouble I know the remedy. I intend to keep the dog and cat."

The late Professor Slingerland very effectively used hydrocyanic acid gas fumigation in exterminating fleas in houses. In one case, where failure was reported, he found on investigation that the house had become thoroughly reinfested from pet cats, which had been left untreated. Fumigation with sulphur is likewise efficient.

The fact that adult fleas are usually to be found on the floor; when not on their hosts, was ingeniously taken advantage of by Professor S. H. Gage in ridding an animal room at Cornell University of the pests. He swathed the legs of a janitor with sticky fly-paper and had him walk back and forth in the room. Large numbers of the fleas were collected in this manner.

In some parts of the southern United States hogs are commonly infested and in turn infest sheds, barns and even houses. Mr. H. E. Vick informs us that it is a common practice to turn sheep into barn-lots and sheds in the spring of the year to collect in their wool, the fleas which abound in these places after the hogs have been turned out.

It is a common belief that adult fleas are attracted to fresh meat and that advantage of this can be taken in trapping them. Various workers, notably Mitzman (1910), have shown that there is no basis for such a belief.

The true chiggers—The chigoes, or true chiggers, are the most completely parasitic of any of the fleas. Of the dozen or more known species, one commonly attacks man. This is *Dermatophilus penetrans*, more commonly known as *Sarcopsylla penetrans* or *Pulex penetrans*.

This species occurs in Mexico, the West Indies, Central and South America. There are no authentic records of its occurrence in the United States although, as Baker has pointed out, there is no reason

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why it should not become established in Florida and Texas. It is usually believed that Brazil was its original home. Sometime about the middle of the nineteenth century it was introduced into West Africa and has spread across that continent.

The males and the immature females of *Dermatophilus penetrans* (fig. 93) closely resemble those of other fleas. They are very active little brown insects about 1-1.2 mm. in size, which live in the dust of native huts and stables, and in dry, sandy soil. In such places they often occur in enormous numbers and become a veritable plague.

They attack not only man but various animals. According to Castellani and Chalmers, "Perhaps the most noted feature is the way



93. *Dermatophilus penetrans*. Much enlarged. After Karsten.

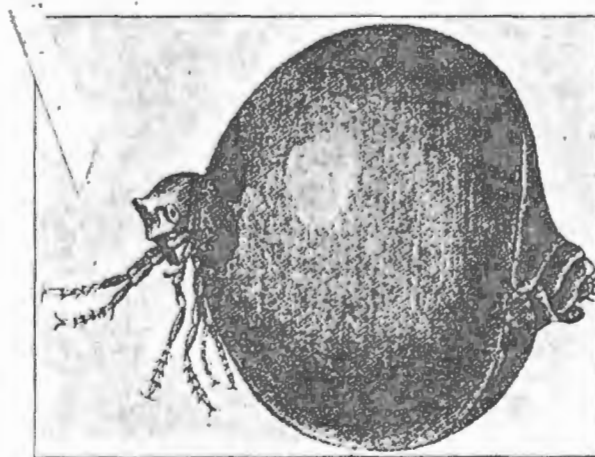
in which it attacks pigs. On the Gold Coast it appeared to be largely kept in existence by these animals. It is very easily captured in the free state by taking a little pig with a pale abdomen, and placing it on its back on the ground on which infected pigs are living. After watching a few moments, a black speck will appear on the pig's abdomen, and quickly another and another. These black specks are jiggers which can easily be transferred to a test tube. On examination they will be found to be males and females in about equal numbers."

Both the males and females suck blood. That which characterizes this species as distinguished from other fleas attacking man is that when the impregnated female attacks she burrows into the skin and there swells until in a few days she has the size and appearance of a small pea (fig. 94). Where they are abundant, hundreds of the

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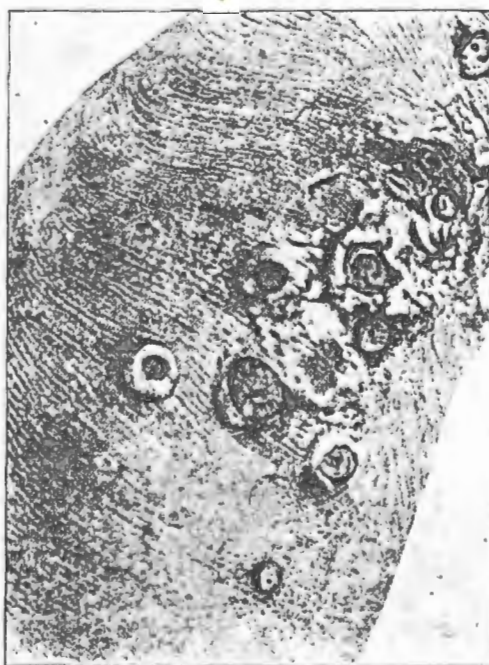
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94. *Dermatophilus penetrans*, gravid female. After Moniez.

pests may attack a single individual (fig. 95). Here they lie with the apex of the abdomen blocking the opening. According to Fülle-



95. Chiggers in the sole of foot of man. Manson's Tropical Diseases. Permission of Cassell and Co.

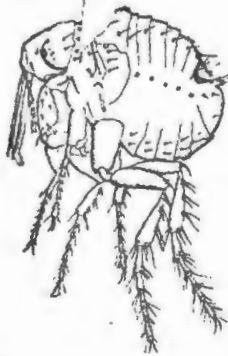
born (1908) they do not penetrate beneath the epidermis. The eggs are not laid in the flesh of the victim, as is sometimes stated, but are expelled through this opening. The female then dies, withers and falls away or is expelled by ulceration. According to Brumpt, she first quits the skin and then, falling to the ground, deposits her eggs. The subsequent development in so far as known, is like that of other fleas.

The chigoe usually enters between the toes, the skin about the roots of the nails, or the soles

Siphonaptera, or Fleas

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of the f, although it may attack other parts of the body. Mense records the occurrence in folds of the epidermis, as in the neighborhood of the anus. They give rise to irritation and unless promptly and aseptically removed there often occurs pus formation and the development of a more or less serious abscess. Gangrene and even tetanus may ensue.



96. *Echidnophaga gallinacea*.

Treatment consists in the careful removal of the insect, an operation more easily accomplished a day or two after its entrance, than at first, when it is unswollen. The ulcerated point should then be treated with weak carbolic acid, or tincture of iodine, or dusted thoroughly with an antiseptic powder.

Castellani and Chalmers recommend as prophylactic measures, keeping the house clean and keeping pigs, poultry, and cattle away therefrom. "High boots should be used, and especial care should be taken not to go to a ground floor bathroom with bare feet. The feet, especially the toes, and under the nails, should be carefully examined every morning to see if any black



97. *Echidnophaga gallinacea* infesting head of chicken. After Enderlein.

dots can be discovered, when the jigger should be at once removed, and in this way suppuration will be prevented. It is advisable,

also, to sprinkle the floors with carbolic lotion, Jeyes' fluid, or with pyrethrum powder, or with a strong infusion of native tobacco, as recommended by Law and Castellani."

Echidnophaga gallinacea (fig. 96) is a widely distributed Hectopsyllid attacking poultry (fig. 97). It occurs in the Southern and Southwestern United States and has been occasionally reported as attacking man, especially children. It is less highly specialized than *Dermatophilus penetrans*, and does not ordinarily cause serious trouble in man.

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CHAPTER XXIX

Diseases Caused or Carried by Mites and Ticks ¹

W. Dwight Pierce

The Arachnid order Acarina, composed of mites and ticks, contains many of the most serious carriers of causative agents of disease. As all ticks are parasitic on animals and derive their entire nourishment from the blood of their hosts, it is naturally to be expected that in this group we will find a great proportion of the carriers of animal blood diseases. The mites are not all parasitic, but there are quite a number of families in which parasitic mites are found, and some of the families are parasitic exclusively in their habits.

The most familiar of all the tick-borne diseases is the disease known as TEXAS FEVER OF CATTLE which has cost the southern states millions of dollars, and has been the cause of restricting the shipment of cattle from southern to northern states. The discovery of the rôle of the tick in the transmission of Texas Fever by Smith and Kilborne of the Bureau of Animal Industry, was one of the earliest discoveries in medical entomology. Since that time the Department of Agriculture, through the investigations of the Bureau of Animal Industry and Entomology has devoted a great deal of attention to this problem. The Bureau of Animal Industry has had charge of the eradication of the cattle tick in America and has succeeded in eliminating this pest from large areas and from at least one state, the State of Mississippi.

In South Africa tick-borne diseases are the principal limiting factors to animal industry. The RELAPSING FEVERS of man in Africa are carried almost exclusively by ticks. In our own country one of the most serious local diseases is ROCKY MOUNTAIN SPOTTED FEVER in the northern Rocky Mountains. The relationship of the ticks and mites to disease can best be shown by an arrangement of these diseases according to their causative organism.

DISEASES CAUSED BY DIRECT ATTACK OF TICKS AND MITES

ACARINE DERMATOSIS or ACARIASIS. A great many different species of mites are capable of causing various types of DERMATOSIS

¹This lecture was prepared for the present edition.

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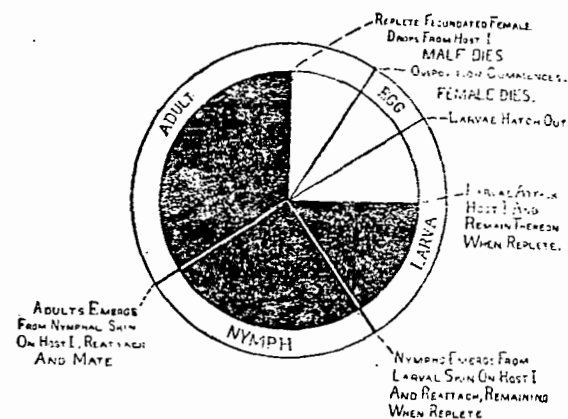
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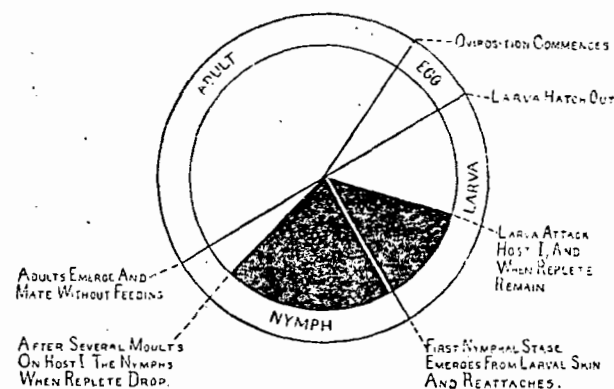
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TICK LIFE CYCLE - TYPE V

THE LIFE CYCLE OF THE GENUS *BOOPHILUS*
(After Nuttall 1911)

FIG. 81.



TICK LIFE CYCLE - TYPE VI

THE LIFE CYCLE OF *ORNITHODOROS MEGNINI*.
(ORIGINAL)

FIG. 85--(Pierce).

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larval stages, and does not reattach during the adult stage. The parasite, if taken up, must be taken up by the larva or nymph and remain in the body during transformation, entering the eggs, thus to be transmitted by the offspring of the tick.

It is quite evident from this that any one who studies the transmission of disease by ticks, must first take into account the life cycles of the ticks which he is studying, in order to arrive at any understanding of the life cycles of the parasites. Perhaps we may learn a valuable lesson from the ticks in our search for the life cycles of parasites in other forms of invertebrates.

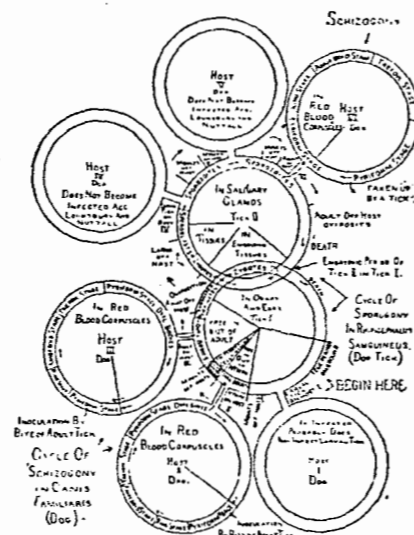
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France. *Ixodes hexagonus* Leach (*reduvius* Audouin), and *I. ricinus* (Linnaeus) Latreille, are suspected to be carriers. The life cycle in the dog was worked out by Nuttall and Graham-Smith (1904-7). The cycle of schizogony is passed in the dog. The free pyriform parasite enters a normal red blood corpuscle and becomes rounded in shape. The parasite throws out pseudopodia and appears as an amoeba. This stage lasts a long time, at the end of which the parasite enters upon a quiescent stage. Finally the organism takes a form called the trefoil stage, in which the main mass of the chromatin, much reduced in size, lies at the base of the two processes. Two nuclei are formed, finally the cytoplasm divides.



LIFE CYCLE OF *BABESIA CANIS*

THE CAUSE OF CANINE MALIGNANT JAUNDICE.

FIG. 78.—(Pierce).

and two pyriform parasites are found lying side by side in one corpuscle. The corpuscle now ruptures and liberates the two parasites.

Christophers has worked out the cycle of sporogony in the tick. When an adult or nymphal tick bites a dog and takes in blood containing the oval parasites, these develop in the gut into round or oval bodies which finally assume the form of a club-shaped body which gradually becomes oökinete. In the adult these oökinetes wander into the ova, while in the nymph they simply pass into the embryonic tissues. In either case they become rounded and form a zygote which breaks up into sporoblasts, and these again into sporozoites which infect the salivary gland of the nymph and the adult of the second generation.

A parent tick having gorged with blood falls to the ground and

other eggs which develop into six-legged larvae. They do not infect the dog, which they attack as soon as possible and on which they remain a few days sucking blood. After dropping off they in due time shed their larval skin and become eight-legged nymphs which again attack the dog, but do not infect it. The nymph, after dropping off, undergoes metamorphosis and sheds its nymphal skin, and becomes the sexually mature tick, which is the only form that spreads the infection, according to Lounsbury (1901), and Nuttall.

Babesia divergens (McFadyean and Stockman), the cause of British RED WATER OF CATTLE, is principally carried by *Ixodes ricinus* (Linnaeus) Latreille, although McFadyean and Stockman succeeded in transmitting the disease by means of *Haemaphysalis cinnabarina punctata* Canestrini and Fanzago (Nuttall, Warburton, Cooper, and Robinson, 1915).

Babesia gibsoni (Patton), cause of BABESIASIS OF THE JACKAL AND DOG, is said by Neumann to be carried by *Rhipicephalus simus* Koch. Patton found infested jackals with *Haemaphysalis birmaniae* Supino (*bispinosa*) and *Rhipicephalus simus* Koch but did not prove that they were infected.

Babesia minense Yakimoff, the cause of BABESIASIS OF THE HEDGEHOG, is said by Doflein to be carried by *Dermacentor reticulatus* (Fabricius) Koch.

Babesia ovis (Babes), the cause of CARCEAG of sheep, is hereditarily transmitted by *Rhipicephalus bursa* Canestrini and Fanzago. The daughter adult tick, developed from a tick which sucked the blood, is the stage which transmits the disease. The disease has been transmitted by *Haemaphysalis cinnabarina punctata* Canestrini and Fanzago experimentally.

Crithidia haemaphysalidis Patton is hereditary in *Haemaphysalis birmaniae* Supino (*bispinosa*) in India.

Crithidia hyalomae O'Farrel is hereditary in *Hyalomma aegyptium* (Linnaeus) Koch in the Sudan.

Nuttallia equi (Laveran), the cause of NUTTALLIOSIS OF EQUINES, was demonstrated by Theiler to be transmitted in South Africa by *Rhipicephalus cecetsi* Neumann. Considerable evidence points towards *Hyalomma aegyptium* (Valladares 1915).

Rossiella rossi (Nuttall), the cause of JACKAL ANEMIA, is thought by Nuttall to be possibly carried by *Haemaphysalis leachi* (Audouin) Neumann.

Theileria parva (Theiler), the cause of EAST COAST FEVER or RHODESIAN FEVER, has been known by Theiler (1903, 1904, 1908) and Lounsbury (1906) to be transmitted by *Rhipicephalus appendiculatus* Neumann, *R. simus* Koch, *R. cecetsi* Neumann, *R. capensis* Koch

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DISEASES OF ANIMAL ORIGIN

Protozoa

Mastigophora: Binucleata: Trypanosomidae

Schizotrypanum cruzi Chagas, the cause of CHAGAS FEVER, normally transmitted by the kissing bugs of the genus *Triatoma*, has been shown by Brumpt to develop in the tick *Ornithodoros moubata* (Murray) Pocock, and by Neiva (1913) to develop in *Rhipicephalus sanguineus* (Latreille) Koch.

Trypanosoma sp. which is supposed to cause a reptilian disease, is carried by *Amblyomma testudinis* (Coquillett) Neumann.

Trypanosoma christophersi Novy is an organism probably native to *Rhipicephalus sanguineus* (Latreille) Koch and was originally recovered from ticks fed on dog.

Mastigophora: Binucleata: Leptomonidae

Some authors are inclined to separate the genera of tick organisms to form the family Piroplasmidae. These organisms do seem to form a rather consistent family which contains the genera *Theileria*, *Nuttallia*, *Babesia*, *Piroplasma*, *Rossiella*, and *Anaplasma*.

Anaplasma argentinum, the cause of ARGENTINE ANAPLASMOSIS of cattle, is carried by *Boophilus annulatus australis* Fuller (*microplus* Canestrini) (Lignières 1914).

Anaplasma marginale Theiler, cause of ANAPLASMOSIS of many African and Australian animals, is transmitted according to Theiler (1910) by *Boophilus annulatus* (*decoloratus* Koch), and according to Castellani and Chalmers by *Rhipicephalus simus* Koch.

Babesia argentinum, cause of Argentine BABESIASIS OF CATTLE, is carried by *Boophilus annulatus australis* Fuller (*microplus* Canestrini) (Lignières 1914).

Babesia bovis Babès (*Piroplasma bigeminum* Smith and Kilborne), the cause of TEXAS CATTLE FEVER which is also known as RED WATER, SPLENIC FEVER, SOUTHERN CATTLE FEVER and under various other names, is normally transmitted by the cattle tick *Boophilus annulatus* (Say) Stiles and Hassall in North America. The first proofs of tick transmission were published by Smith and Kilborne (1893). Crawley (1915) believes the organism is pathogenic to this tick. The organism may also be transmitted by *Boophilus annulatus australis* Fuller (*decoloratus* Koch) in South America, Cuba, Porto Rico.

**Babesia bovis* and *B. bigeminum* are separated by some authors as two distinct species, *bovis* causing the European disease, and *bigeminum* the American.

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Philippines, and Australia, according to various authors, and by *Boophilus annulatus australis* (*microplus*) in South America (Lignières), and *B. annulatus decoloratus* and *Rhipicephalus capensis* Koch in Africa. Carpano (1915) suspects *Hyalomma aegyptium* (Linnaeus) Koch to be the carrier of *Babesia annulatus*, a synonym of *bovis* which is recorded as the causative organism of MEDITERRANEAN COAST FEVER OF CATTLE.

The first contributions to the life history of this organism were made by Smith and Kilborne. It is found in the blood of the animal hosts in the first stage, being inside the red blood cells near its margin, and is non-motile and pale. This single body develops incompletely into two small roundish bodies which are partially connected by a narrow interconnecting strand. In the next stage the minute, double, rounded bodies become enlarged and spindle-shaped. They probably remain attached, however. The two bodies enlarge uniformly and assume a pear-shaped appearance. At this stage of the life cycle, the disease is in its most acute form. The parasites occupy nearly one-fourth of the body of the red blood cells and from 0.5 to 2 per cent of the red cells are usually invaded. The blood cells finally break up, liberating the parasites which may be observed as free bodies in the circulation. The parasites are taken up by the tick, according to Koch, in the red blood cells. In the body of the tick the parasites leave the red cell and become long and club-shaped. From the club pseudopodia project. This club then becomes spherical and immense numbers of amoeba-like forms appear, which are said to grow into clubs. The disease can only be transmitted by seed ticks, that is, by the first stage of the tick. The adult tick which sucked up the infected blood drops to the ground and lays its eggs. The organism passes into the eggs and is transmitted to other animals by the offspring of the tick which became infected. The disease can be given to a host almost immediately after attachment. The tick remains on the animal throughout its development (Mohler 1905).

Babesia caballi (Nuttall), the cause of EQUINE BILIARY FEVER, is considered by Marzinowski and Bielitzer (1909) to be carried by *Dermacentor reticulatus* (Fabricius) Koch in Russia. According to Valladares (1914), there is a possibility that *Hyalomma aegyptium* (Linnaeus) Koch is the carrier in India.

Babesia canis (Piana and Galli-Valerio) the cause of a CANINE BABESIASIS, also known as MALIGNANT JAUNDICE OF DOGS, is transmitted by several ticks. The life cycle has been traced in *Rhipicephalus sanguineus* (Latreille) Koch by Christophers in India (fig. 78). Lounsbury proved the transmission of the disease in South Africa by *Haemaphysalis leachi* (Audouin) Neumann. According to various authors *Dermacentor reticulatus* (Fabricius) Koch carried the disease in

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an important rôle in producing FISTULOUS WITHERS. He considers *Dermacentor albipictus* Packard as the worst offender, but considers *D. andersoni* Stiles (*venustus* Banks) as a cause. *D. albipictus* is commonly called a winter tick and in some regions of British Columbia where poll evil and fistulous withers are common, horses are heavily infested with these ticks. The favorite site of attachment is along the whole length of the mane from the poll to the withers. At the point of attachment there is often a necrotic spot if the tick has been attached for a few days. It is easy to see that these necrotic spots should be a favorite point of entrance for bacteria.

It is quite probable that most of the cases of abscesses and irritations resulting from tick bites are due to secondary infections by bacteria which may possibly be mechanically introduced by the tick itself. No one has given this question serious attention.

DISEASES OF UNKNOWN ORIGIN

There are quite a number of instances of so-called tick fever caused by the bite of ticks, of which the exact cause is unknown. Among these are unnamed TICK FEVERS caused by *Ornithodoros savignyi* Audouin (Koch) and *Hyalomma aegyptium* (Linnaeus) Koch.

HEART WATER, a disease of sheep, caused by a filterable virus, is transmitted by *Amblyomma hebraeum* Koch.

The TICK FEVER OF MIANA is caused by the bite of *Argas persicus* Oken.

INTERMITTENT FEVER of Wyoming, which is possibly identical with Rocky Mountain Spotted Fever, is thought by Castellani and Chalmers to be caused by *Dermacentor andersoni* Stiles (*venustus* Banks).

ROCKY MOUNTAIN SPOTTED FEVER, a disease characteristic of the Rocky Mountains of Montana and Idaho and occasionally other nearby states, was proven by Ricketts to be transmitted by the tick *Dermacentor andersoni* Stiles (*venustus* Banks), by *D. variabilis* (Say) Banks and possibly by *D. modestus* Banks.

The first scientific article in which the tick is mentioned as a possible carrier of this disease was published by Wilson and Chowning in 1902. They subsequently published the reports of their investigations but they did not prove that the tick was actually the transmitting agent. Anderson (1903) was so convinced that the tick was the cause of the fever that he published an article calling it the SPOTTED FEVER or TICK FEVER of the Rocky Mountains. Stiles in 1904 did not attribute the disease to ticks. Finally Ricketts in 1906 began a thorough investigation

of the cause of the disease and proved transmission of the disease to a guinea pig by *Dermacentor andersoni* Stiles (*occidentalis* Stiles, not *hax*). This preliminary report by Ricketts was followed by numerous other papers by himself on the subject, until he had definitely proven the relationship of the tick to the disease. The organism causing spotted fever has just been described. Wilson and Chowning described *Piroplasma* as the causative organism, but their work has not been corroborated by others. Very recently Wolbach (1919) has found bodies somewhat similar to the Rickettsia bodies found in typhus fever and trench fever. He describes his organism as *Dermacentroxenus rickettsi* Wolbach, but is uncertain as to its location in classification. It is intracellular in mammal and tick, and intranuclear in ticks. Two multiplication forms and an infective form are found in the tick, and only the latter is regularly found in mammals. Wolbach's volume is the latest and most complete treatise on all phases of the disease and is well illustrated.

Mayer (1911) conducted transmission experiments and was successful in transmitting the disease by *Dermacentor marginatus* Banks, *Amblyomma americanum* (Linnaeus) Koch and *Dermacentor variabilis* (Say) Banks.

The rôle of wild animals in acting as reservoirs for the disease has not been definitely determined although several wild mammals have been shown to be susceptible. It is probable that it is by this means that the disease is perpetuated. The ticks which carry the disease are normally found on wild animals in the immature stages and the adults usually engorge on the larger domestic animals and to some extent on the larger wild mammals. The Rocky Mountain Spotted Fever is transmitted hereditarily by the tick. Control of the disease must be effected by destruction of the adult ticks on domestic animals, reduction of the numbers of wild hosts, and prevention of tick attack on man.

TSUTSUGAMUSHI DISEASE, sometimes called JAPANESE RIVER FEVER or KEDANI DISEASE, has been proven to be carried by the mite *Leptus akamushi* Brumpt (*Trombidium*). Kitashima and Miyajima have proven that this disease is not caused by the bite of all mites of this species, but only by certain ones, and consider that the evidence is sufficiently strong to assume that the disease is caused by a non-filterable virus which can be inoculated by the mites only after they have become infected. They conducted a large number of experiments to prove the rôle of the mite. The field mouse, *Microtus montebelli*, is susceptible and is believed to be the important natural host of the virus. (It is interesting to note that another Japanese disease, Seven Day Fever, caused by *Leptospira hebdomadis* Ido, Ito and Wani has the same mouse, *Microtus montebelli* as its reservoir.)

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the site of the tick's bite. In some cases which have been reported the tick was not removed and in these the paralysis progressively involved the whole body until reflexes and control of the sphincters were lost; death ensued. Abscesses following a tick bite are probably due to the head of the tick remaining in the wound. The symptoms suggest tick-bite paralysis but they may be distinguished from cases of that disease by the invariably transitory nature of the paralysis. The tick parasite never leaves permanent disability. Various doctors practicing in the Northwest have described cases, some of which have been fatal. In cases of paralysis it is always well to make a thorough search of the body, especially in the vicinity of the spinal column, for the ticks. They are commonly found in the hair at the base of the head. The exact cause of the paralysis is unknown, but it is believed that it is caused either by the injection of a specific poison into the body by the tick, or by the reactions which take place, forming poisons during the presence of the tick's head in the body. The only treatment necessary is the removal of the tick by excision in order to make sure that the mouth parts are removed, and the dressing of the wound antiseptically. Purgatives and stimulants should be given. *Dermacentor andersoni* also causes a paralysis of animals similar to that in man; in the case of sheep the effect on the body is a loss of balance, causing the sheep to fall in places from which they cannot extricate themselves. If the tick is removed in time the animal will recover.

South African TICK PARALYSIS in animals is caused by the bite of *Ixodes pilosus* Koch which attacks sheep principally. The effect of this paralysis is to cause the sheep to become very unsteady on their feet and to lie down frequently. They seem to recover rather rapidly, death being usually caused by their becoming prostrated in the open where they fall victims of jackals. There are no fever reactions. Dipping with Cooper's Dip is considered a very effective control measure.

HUMAN TICK BITE FEVER of Lourenço Marques is caused principally by the larva of *Amblyomma hebraeum* Koch but occasionally by *Rhipicephalus simus* Koch and *Boophilus annulatus* (Say) Stiles and Hassell² and *B. annulatus* (*decoloratus* Koch). The patient at first complains of general weakness, muscular pains and especially of considerable difficulty in moving his arms and legs. The glands in the neck become swollen in a short time, those situated in the nape of the neck.

¹Mr. Bishopp writes that he prefers *Margaropus* to *Boophilus* for this tick and its allies. My reasons for adopting *Margaropus* are as follows:

1. *Margaropus* Karsch and *Boophilus* Curtice are considered by Nuttall, Warburton, Cooper, and Robinson (1911) to be two distinct genera. The type of the former is designated by them as *Margaropus winthemi* Karsch, and of the latter *Boophilus annulatus* (Say) Curtice.

2. *Boophilus annulatus* is a name well established in medical literature. (W. D. Pierce.)

chiefly involved. The patient suffers from severe occipital headache and considerable rigidity of the muscles of the nape of the neck, so that the head may be turned to one side as in torticollis. The superficial glands in the groin and axilla are found to be enlarged and acutely painful. The acute neck symptoms begin to subside from the eighth to tenth day and recovery takes place spontaneously, but the glandular enlargement persists a month or more after recovery. The glands become hard and painless.

AUSTRALIAN HUMAN TICK PARALYSIS is caused by either *Ixodes ricinus* (Linnaeus) Latreille or *Ixodes holocyclus* Neumann and is very similar to the American tick paralysis. Eaton considers that there are three possibilities as the cause of the paralysis: pre-formation of the poison by the tick, development of the infective organism in the blood, or liberation mechanically or biologically (by bacterial introduction) at the site of the bite, of some poison subsequently absorbed.

DISEASES CARRIED BY MITES AND TICKS

Ticks and mites are the carriers of many diseases.

DISEASES CAUSED BY PLANT ORGANISMS

There are undoubtedly many cases of SEPTICEMIA due to the introduction of plant organisms at the site of the bite of the tick. These are most likely to be streptococcal and staphylococcal infections. For instance, the bite of *Argas reflexus* (Fabricius) Latreille has been known to give rise to FURUNCULOSIS caused by *Staphylococcus pyogenes* (Nuttall, Warburton, Cooper, and Robinson, 1908). *Ixodes ricinus* (Linnaeus) Latreille may also carry infections of *Staphylococcus pyogenes* (Nuttall, Warburton, Cooper, and Robinson, 1911).

Demodex folliculorum Simon, the blackhead mite, causes an irritation giving rise to papules which become infected with *Bacillus necrophorus*.

Jarvis has just published an article in which he claims that EPIZOOTIC LYMPHANGITIS is an inoculable disease through the agency of the ticks of the genus *Amblyomma*. The disease is characterized by supuration, ulceration, and necrosis. He believes that the lesions are caused by a variety of micro-organisms including the Priesz-Nocard organism, the *Cryptococcus farciminosus*, the *Bacillus necrophagus*, and Staphylococci, and that these organisms are introduced through the agency of the mouth parts of the ticks which are very long and pierce the whole integument, reaching the subcutaneous layers where the bacteria can easily set up lesions.

Hadwen has just published an article in which he shows that ticks play

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БЕЛ ДООПШЕНА НАВУЧЕНА

causes white tubercles on the skin of swine in the United States and Canada; *Demodex bovis* Stiles causes swellings in the hide of cattle in the United States and other countries, damaging the hide.

GUANO ITCH of man and dogs is caused by *Tydeus molesta* M. in Peru and Belgium; it is found in guano.

SEBACEOUS TUMORS in birds are caused by species *Harpagophthorichus*. *H. longipilus* Banks attacks the cross-bill. Mice are attacked by the mites *Psorergates simplex masculinus* Mich., which lives in ear canals beneath the surface of the skin, and *Myobia musculi* Schrank which develops in the hair follicles.

ACARIASIS OF THE SENSE ORGANS. OTOACARIASIS is caused in man by *Cheyletus eruditus* Schrank and *Acaropsis mercurialis* Laboulbène which attack the external auditory meatus. *Rhizoglyphus parasiticus* has also been recorded as causing Otoacariasis. *Psoroptes cuniculi* Mègnin causes a rabbit ear mange which may result in death. *Otodectes cynotis* causes an otoacariasis of the dog and cat, which torments the animals, resulting in convulsions and fits. *Demodex folliculorum* Simon is also credited with causing otoacariasis.

Some of the ticks are also responsible for attacks of otoacariasis, as for instance the spinose ear tick *Ornithodoros megnini* (Dugès) Neumann, which very commonly attacks the ears of cattle and horses, and sometimes man in the southwestern United States.

A fatal otoacariasis in the cow is charged to *Dermanyssus gallinæ* Redi, but there is reason to question this.

OCULAR ACARIASIS of the cornea may also be caused by *Dermanyssus gallinæ*.

INTERNAL ACARIASIS. CATARRHIAL INFLAMMATION which may produce ASPHYXIA in chickens may be caused by *Sternostomum rhinoletum* Trouessart and by a *Rhinonyssus* in birds. BRONCHIAL INFLAMMATION which may produce asphyxia may be caused by *Halurachne americanæ*, *H. attenuata*, and *H. halichacri*, all of which attack seals. INFLAMMATION OF THE LUNGS, which may produce asphyxia, may be caused by *Pneumonyssus simicola* of the monkey. *Cyrtolichus nudus* Vizioli occurs in the air passages of chickens and turkeys, penetrating the tissues, and may produce asphyxia. *C. sarcophagæ* Héguin also attacks the air sacs in fowls.

Nephrophages sanguinarius Miyake and Scriba is a doubtful parasite passed in bloody urine. *Carpoglyphus alienus* Banks has been found in purulent urine. A case of a cyst in the testis containing *Histiogaster spermaticus* Trouessart is recorded from India. *Cyrtolichus sarcophagæ* Héguin is sometimes found in the liver and kidneys of the fowl. *C. nudus* Vizioli is suspected of producing PERITONITIS and ENTERITIS in chickens and turkeys. *C. banksi* Wellman also produces an internal

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in the squirrel. *Laminosioptes cysticola* produces a calcareous mass in the subcutaneous tissues of chickens.

GENERAL EFFECTS OF TICK BITE. The mites in attacking usually attack in numbers, or if individually, will be found to pierce into the skin, but the ticks merely attach themselves to the skin and draw blood. Tick bites are very likely to cause a PRURITIS which in some cases will be painful for months or sometimes years. This is especially true in the case of *Argas reflexus* (Fabricius) Latreille which causes a painful bite marked for years by a cicatrix at the site of the attack. *Argas brumpti* Neumann causes a pruritis the site of which remains indurated for years. The bite of *Ornithodoros coriaceus* Koch is very painful; the bites are slow healing. The bite of *Ornithodoros turicata* (Dugès) Neumann may cause dermatitis and lymphangitis. The bite of *Ixodes ricinus* (Linnaeus) Latreille may cause in man abscesses, edema, lymphangitis, and fever; it may penetrate beneath the skin and produce a tumor. The bite of *Ixodes (Ceraticodes) putus* (Picard-Cambridge) Neumann is painful to man. It normally attacks birds. The bite of the "conchuda," *Ixodes bicornis* Neumann, is sometimes fatal to infants.

TICK PARALYSIS. The bite of certain ticks causes paralysis of man and animals. The NORTH AMERICAN HUMAN TICK PARALYSIS is caused by the same tick which causes Rocky Mountain Spotted Fever, *Dermacentor andersoni* Stiles (*venustus* Banks)² in the northwestern States, and British Columbia, but a case is recorded from California caused by *Ornithodoros coriaceus* Koch. Todd has described a typical case of paralysis in children as follows: An active and apparently healthy child suddenly develops a paresis or paralysis of the legs; neither abnormal temperature nor any other symptoms of paralysis is constant. After the discovery of the tick and its removal the symptoms disappear in a few hours with a possible exception of a more or less local reaction, often probably due to a secondary bacterial infection at the bite.

²In view of the contention of Mr. Bishopp that *venustus* is the name of the fever tick it is necessary to give my reasons for the adoption of *andersoni*.

Dermacentor venustus Marx in Neumann (1897) is cited as an undescribed synonym of *D. reticulatus* Fabricius.

In 1903 Stiles named the Rocky Mountain Spotted Fever tick as *D. andersoni*, strengthening his description in 1908 and 1910.

In 1908 Banks drew up the description, as a new species, of *Dermacentor venustus* (Marx) from the Marx material, which was subsequently examined by Stiles and found to consist of three lots of material of at least two species. Stiles definitely picked from Banks' type material Marx No. 122 as type of species *D. venustus*. Since both Marx and Banks confused more than one species and neither designated a type from the material, Stiles' type designation is valid.

In 1910 Stiles differentiates between the two species *andersoni* and *venustus*. Ever if he should be found to be wrong in considering these as two species, *andersoni* antedates *venustus*. But in order to set this question at rest an appeal has been made to the International Commission of Zoological Nomenclature for a ruling on the name of this tick. (W. D. Pierce.)

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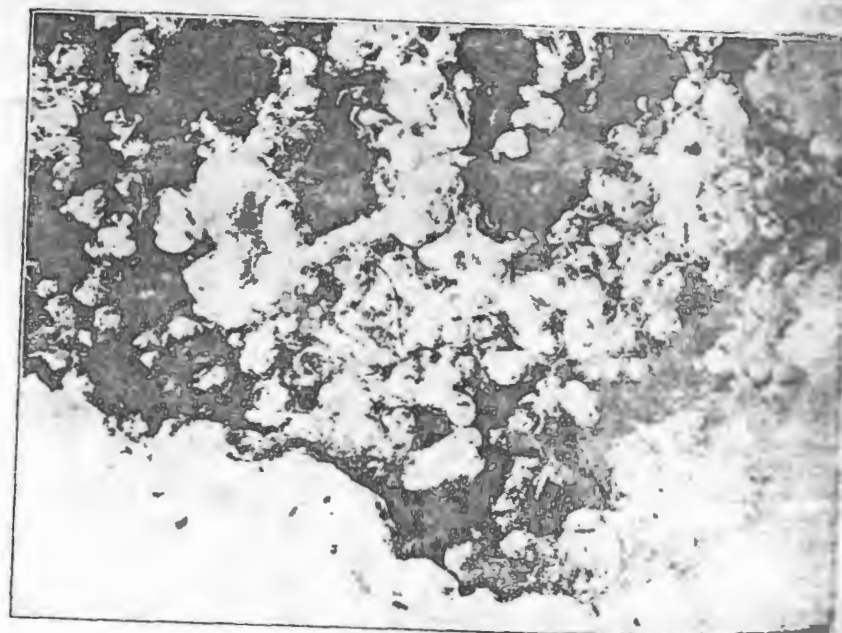
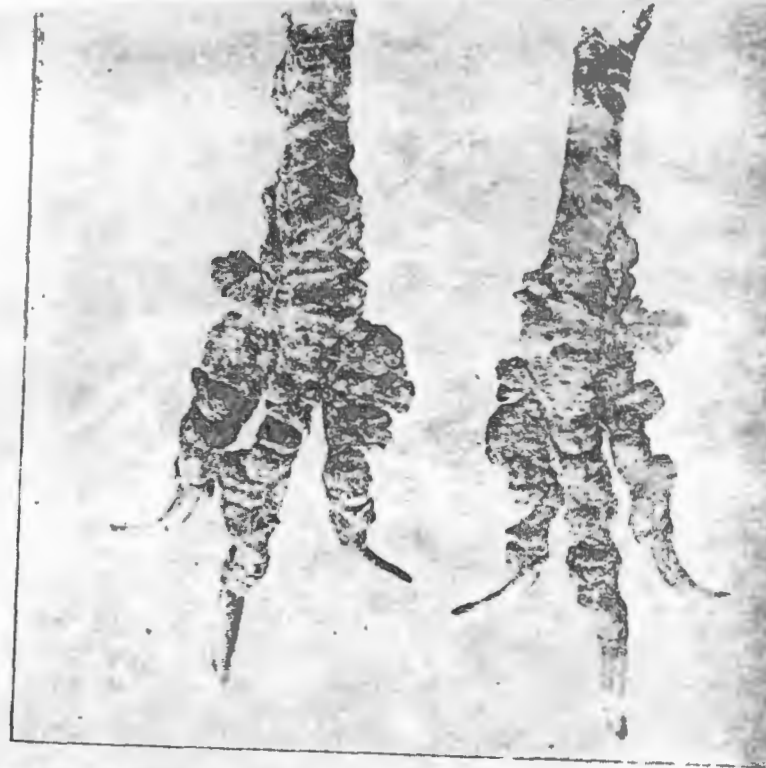


PLATE XXIV.—Scaly leg mite on chickens
FIG. 1 (Upper).—Scaly leg on chicken, caused by mite attack. FIG. 2 (Lower).—
leg mites, greatly enlarged. (Bishopp.)

from a tick. The related species, *Cnemidoptes gallinae* R. L., causes the
pluck their feathers. The mites work at the base of the feathers



PLATE XXV.—Dipping scaly legs of chicken in crude oil (Bishopp.)

are called depluming mites. These mites are controlled by dipping
crude petroleum (plate XXV).
DEMODECTIC MANGE, when caused by *Demodex folliculorum*
mon, gives rise to BLEPHARITIS, SEBORRHOEA or BLACK-
HEADS. Many animals and man are attacked by this mite. Probably
majority of persons harbor this mite. Demodectic mange is a common
and practically incurable disease in dogs. *Demodex phylloides* Csoker



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Minor Notes

SULFUR SOAP PASTE IN THE TREATMENT OF SCABIES

ROSE A. NOLAN, M.D.

Commander, Medical Corps, United States Navy

SAN DIEGO, CALIF.

The present methods of treatment for scabies, in which the use of sulfur ointment plays a major role, are not without economic disadvantages, such as loss of time from studies or other occupations and damage to clothing from ointment bases. This economic loss and the discomfort attendant on the treatment have been overcome by the use of a bland paste soap as a vehicle for the sulfur, which is applied as a copious lather and allowed to dry, leaving a film of sulfur on the body. For treatment, this procedure is repeated for three days, daily changes of underwear being prescribed. When necessary, as in barracks, it is possible to give the treatment to a large number of men in a short time by instructing them, in formation, to each apply the soap paste to the back of the man in front, lather well and then cover himself thoroughly with fresh lather. One application is sufficient for prophylaxis of an exposed person.

The sulfur soap paste I have used contains 18 per cent sulfur, whereas compound ointment of sulfur N. F. contains 15 per cent, and only about 4 Gm. is required for satisfactory coverage. Since about 85 Gm. of sulfur ointment (equivalent to 12.8 Gm. of sulfur) is ordinarily used, in my opinion the soap base preparation containing only 0.72 Gm. of sulfur is preferable because of lessened danger of dermatitis. I believe that less than 0.32 Gm. of sulfur evenly distributed in a thin soap film over the surface of the body produces sufficient hydrogen sulfide to discourage the itch mite from lodging in the joints of the garments and in the underclothing. It was noted that when sulfur was mixed in a soapy solution, bubbles blown and held before a light made it possible to count the granules of sulfur as they gyrated rapidly, exposing their respective prismatic sides to the atmosphere. Each granule was separate and distinct, and when the bubble was allowed to touch the skin the resulting collapse diffused a thin layer of sulfur on the surface of the body. Dispersion in a lather therefore makes possible wide coverage by small quantities of activated sulfur. Comparative determinations were made of production of hydrogen sulfide and of its penetration of clothing when sulfur was applied to the body in the new soap base and in the usual grease bases. It was found that the test substances, lead acetate paper and silver-foil, when carried in the pockets were discolored less rapidly when the grease base was used. Thus I attribute to the fact that the granules of sulfur must free themselves from their coating of grease before noticeable action takes place.

I have used this preparation and method of application on large numbers of patients under varying conditions ranging from service with expeditionary forces in tropical countries to health surveys of rural schools in the United States, and I have found the entire procedure to be exceedingly simple, efficient and inex-

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SUMMARY

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A method of treatment and prophylaxis of scabies is described, consisting of the application for three days of a sulfur soap paste lather. One application suffices for prophylaxis. The use of a soap lather as a vehicle for dispersion of sulfur makes it possible to cover the body with less sulfur than is required with greasy ointment bases.

The likelihood of producing a sulfur dermatitis is diminished by the small quantity of sulfur required.

Damage to clothing and discomfort due to ointment base vehicles are absent in the treatment with sulfur soap paste.

This method is well adapted to treatment and prophylaxis of large numbers of persons in a short time.

U. S. S. Dobbin, Flagship, Destroyers' Scouting Force.

TREATMENT OF LYMPHANGIOMA CIRCUMSCRIPTUM WITH SCLEROSING SOLUTION

J. L. GRUND, M.D., BOSTON

Various forms of treatment have been recommended for the removal of lymphangioma circumscriptum, radical excision, electrolysis and applications of radium being among those most commonly employed, with varying results. The following is a brief description of the effect of treatment of this form of nevus with a solution of quinine hydrochloride and ethyl carbamate.

A boy aged 13 was seen in September 1936 because of a raised translucent lesion the size of a 25 cent piece and of irregular shape on the middle part of his back. It had been present since birth and conformed clinically with lymphangioma circumscriptum. A year previously a plaque of radium had been applied once and had produced no change.

An injection of 1 cc. of a solution of quinine hydrochloride and ethyl carbamate was introduced into the nevus. Four days later the lesion was replaced by a flat blackish red, slightly necrotic-appearing area of similar size. This was soon replaced by a thin crust. Two weeks after the treatment a small pink spot the size of a 5 cent piece indicated the former location of the nevus. At the time of writing (July 1937) the lesion has not returned, and only a barely perceptible scar can be noted.

The immediate effect of the treatment in this case, together with its simplicity and the excellent cosmetic result obtained, warrants its trial in other similar instances.

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Manitoba during the year 1936, the Department of Health and Public Welfare have come to the following conclusion:

That as the State ultimately may have to support most of the permanently and totally disabled by Poliomyelitis, it is in the interest of the State that it should make provision for:

- (i) Early and adequate diagnostic and treatment facilities.
- (ii) An adequate supply of convalescent serum readily available to every practicing physician.
- (iii) Consultant diagnostic service for cases of residual paralysis.
- (iv) Any corrective treatment and appliances required for indigent persons.

A NEW METHOD OF TREATING SCABIES*

By COMMANDER ROGER A. NOLAN, M.C., U.S. Navy

(With one illustration)

ONE may say about Scabies that it is one of the few diseases in the realm of medicine where the cause of the hospitalization, time lost from duty is not due to the disease per se but to the treatment of the disease.

If we had at our disposal a form of treatment of this disease—specific, efficient, and allowing the patient to be ambulatory, and at the same time preventing the infestation of others we would have no cause for hospitalization. The disease Scabies is a benign, simple, though widespread prevalent one. Any of its complications are the result of missed diagnosis; no treatment; poor choice of treatment; and poorly administered treatment.

In brief and without going into detail concerning this common parasitic disease it is readily discernible that the pith of the situation is the need of a method of treatment which will be one and at the same time curative; of short duration; prevent the disease in others; and in addition be pleasant and clean to the patient. Prompt control of Scabies will do much to lower the incidence of epidemic impetigo which is frequently associated with unsuspected and untreated Scabies.

Treatment: Present method of treatment in which the use of salicylic ointments play a major rôle are *not* without economic disadvantages such as loss of time from school attendance or normal occupation and loss or damage to clothing and bed linen from ointment bases. The economic loss and discomfort to the patient has been overcome by the

* Read at the Forty-fifth annual convention of the Association of Military Surgeons of the U.S., Los Angeles, Calif., October 15, 1937.

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use of a bland paste soap as a vehicle for the flowers of sulfur which combined is applied as a copious lather and allowed to dry, leaving a sulphurated film on the body. For treatment this procedure is repeated for three days, with daily changes of underwear. When necessary, as in schools or barracks, it is possible to give the treatment to a large number of men in a short time by instructing them, in formation, to apply the soap paste to the back of the man in front, lather well, and then cover themselves thoroughly with fresh later. One application of Sulfur-foam is sufficient for prophylaxis of exposed individuals.

The sulfur soap paste contains 18% sulfur, as compared with the official ointment containing 15%, and requires only about four grammes for one satisfactory body coverage. Since about 85 grammes of sulfur ointment is ordinarily used to accomplish the same and contains 12.8 grammes of sulfur, it is believed the soap base preparation containing only 0.72 grammes of sulfur per treatment to be preferable because of diminished danger of dermatitis due to sulfur excess. Experience has demonstrated that less than one gramme of sulfur, evenly distributed in a thin soap film over the surface of the body, will produce sufficient hydrogen sulfide to discourage the itch mite from lodging in seams and under-clothing. It was noted that when sulfur was mixed in a soapy solution, bubbles blown and held before a light permitted the counting of sulfur granules as they gyrated rapidly exposing their respective prismatic sides to the atmosphere. Each granule was separate and distinct, and when the bubble was allowed to touch the skin the resulting collapse diffused a fine layer of sulfur soap foam on the surface of the body. Dispersion in a lather therefore makes possible wide coverage by small quantities of activated granular sulfur which sublimates best at temperatures ranging from 95 to 110 degrees F., body temperature is within this range. Comparative determinations were made of hydrogen sulfide production and its penetration of clothing from sulfur applied to the body in the new soap base and in the usual grease bases. It was found that the test substances, lead acetate paper and silver foil, when carried in the pockets were discolored less rapidly when the grease base



Application of sulphur-foam.

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was used. This was attributed to the fact that the sulfur granules must first free themselves from their coating of grease before noticeable therapeutic and activation takes place.

This preparation and method of application has been used on a large number of individuals under varying conditions ranging from service with expeditionary forces in tropical countries to rural school health surveys in the United States and the entire procedure was found to be exceedingly simple, efficient, and inexpensive.

To summarize: 1. A method of treatment and prophylaxis of Scabies is described, making use of the application for three consecutive days of a sulfur soap paste lather. One application suffices for prophylaxis.

2. The use of a soap lather as a vehicle for dispersion of sulfur makes possible coverage of the body by less sulfur than is required by the grease ointment bases.

3. Likelihood of production of a sulfur dermatitis is diminished the smaller quantity of sulfur required.

4. Damage to clothing and bed linen, and discomfort due to ointment base vehicles is absent in the sulfur soap paste treatment.

5. This method is well adapted to treatment and prophylaxis of large population masses in a short time when epidemic Scabies exists.

When using a so-called ointment on the skin, that which is used has no therapeutic value and only acts as a catch for dust and debris. It is the therapeutic properties in contact with the skin or lesion that matters; if this be so, a bland foam soap base containing therapeutic properties applied as a soap foam gives us cleanliness and controlled therapeutic adherence to the skin as the foam dries and becomes a thin film.

To conclude: The factors that are present which go to make this method of treatment of Scabies efficient are:

1. The presence of a specific (Sulfur).
2. The instant activation of Sulfur when brought in body contact with an alkali as in a soap base.
3. The freeing and separation of sulfur granules permitting instant individual activation of same when brought in contact with a weak alkali in solution.
4. The continued activation of the already activated sulfur granules when brought in contact with the alkaline external secretions of the skin.
5. The continuous production of hydrogen sulphide gas which is lethal to the mite.
6. This idea would be of further value in epidemic typhus, etc.

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measles, spotted fever, plague, and like conditions where insect repellent is a distinct prophylactic factor.

DISCUSSION BY LT. COMDR. JOHN LUTEN, M.C., U. S. NAVY

Scabies and our little friend the itch mite, particularly the female, *Sarcoptes scabiei*, scientifically known as the *Acarus scabiei*, is an old, old friend of the medical profession and was generally attributed by medical historians to have been discovered by Bonomo, of Leghorn, Italy, in 1687.

We have been scratching through several hundred years since the cause of scabies was known and perhaps many hundreds of years before that time from our unpleasant and intimate association with our mole skin companion "Lousy Joe" who certainly does not respect age or station in life.

Sulphur is the classical remedy in the treatment of scabies but, as Dr. Nolan has pointed out, has the objectionable feature when used strong enough, to set up a dermatitis of its own and not uncommonly an allergic dermatitis, particularly when used in connection with other drugs.

We have cured the scabies but the patient continues to itch, scratch and burn from our cure, the doctor actually itches in sympathetic reflex and our whole staff itches. It then behooves us to use our soothing lotions until we have cured the dermatitis. Both the doctor, staff and patient are happy despite the time consuming element of curing both. I dare say that practically everyone sitting here has had this experience whether we have used sulphur combined with Balsam of Peru, Beta-naphthol, the so-called Danish plan of treatment, Cresol derivatives, stotax, or the parasitocides.

For approximately the past 80 years the medical profession has been making little advancement in the therapy of scabies. The treatment currently used is messy, uncomfortable to the patient, objectionable to his friends and as already mentioned usually produces a dermatitis. Dr. Nolan's plan of treatment offers us a real step forward in treating scabies and has removed probably all of the objectionable features as well as offering us a quick cure and a simple prophylaxis. The ingenuity which he has demonstrated in working out this treatment, the simplicity of the method and the high effectiveness with a minimum loss of time which is certainly a most desirable feature to those associated with military forces, is most commendable. Dr. Nolan is to be congratulated.

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CHIGGER MITES*

Chigger mites or "chiggers"¹ are the larval forms of various species of mites belonging to the family Trombididae, commonly known as harvest mites. Many different species of chiggers are known to attack vertebrate hosts, but only two chigger mites attacking man have been recognized from the United States, one, the common North American chigger² and the other a closely related form found in the northern part of the Mississippi Valley.

Description and distribution.—The chigger or larva of the common North American species is oval, bright red, and, as in the first or larval stage of all mites, possesses only 3 pairs of legs. In the unfed

*A leaflet on this subject is available and may be obtained by addressing the Surgeon General, U. S. Public Health Service, Washington, D. C.

¹The term "chigger," with variations in spelling (chigoe, jigger, etc.), is also applied to a tropical fly, *Tunga penetrans*, but usually in this country the term is used to designate the larval forms of the trombidid mites.

²Our common North American chigger attacking man is known under the scientific name of *Trombidium* *rileyi* Oudemans, 1909. In order to aid the reader in tracing the species under its scientific name, the following medical and zoological literature, a list of synonyms follows:

Lept. irritans Riley, 1873 (not *Lept. irritans* Lucas, 1847).
Trombidium irritans (Riley) Mulsant, 1850 (in part).
Trombidium irritans (Riley) Brumpt, 1912.
Trombidium irritans (Riley) Ewing, 1920.
Lept. irritans (Riley) Mulsant, 1850.
Trombidium irritans (Riley) Mulsant, 1850.

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larva. It measures about 150 microns in width, and is scarcely visible to the naked eye. The legs and surface of the body are covered by numerous feathered hairs. The mouthparts consist of a pair of hooked and ventrally barbed fingerlike mandibles, and 2 five-jointed palpi, each of which is provided with a claw divided into 2 prongs at the tip. The adult is a large red hairy mite, with the usual 4 pairs of legs, and with a marked constriction in the anterior portion of the body. Unlike the larval form it is not parasitic but is a scavenger, living largely on the fecal matter of arthropods and on woody decaying substances. Eggs are laid in the ground and the chiggers hatch in the spring soon after warm weather begins.

Chiggers have a widespread distribution in the United States, occurring from Long Island to Mexico and from the Atlantic coast to the Rocky Mountains. They have been found in low lands and well up in the mountains wherever there is rough growth of weeds and shrubbery. They may be encountered from the latter part of April until the last of October, depending upon conditions of temperature and moisture. In the southern United States they may begin to cause annoyance early in May, while in the northern part of their range they seldom appear before the middle of June.

The North American chigger is not only a pest of man but it has been reported as attacking a wide range of vertebrates, including domestic animals, small mammals, birds, and reptiles. It is an important pest of poultry, frequently causing the death of young chickens.

Method of attack.—Chiggers attach themselves to the surface of the skin by means of their mouthparts and feed much as do ticks. They apparently feed upon epidermal tissue liquefied by a secretion which they themselves inject into the skin. When they become fully engorged they drop off. The localization of chigger attachment, to quote one author, is determined by two factors, the tightness of the clothing at certain parts of the body and the thickness of the skin. Experiments by the same writer have shown that chiggers attack by preference where the skin is very thin and the flesh wrinkled or tender. Because of their size, 150 microns in width before they have become engorged, chiggers are unable to enter the pores of the skin (which range from 20 to 50 microns in diameter), but they frequently attach at the mouth of hair follicles. Although it is widely believed that chiggers burrow into the skin and embed their entire body, this method of attack must be extremely uncommon; they would be unable to accomplish such an invasion except in instances where a large enough opening in the skin was already present.

Symptoms.—An intense itching apparently due to the liquefying secretion injected by the chigger, develops within the first 24 hours after exposure, and this is followed by a breaking out of wheals or

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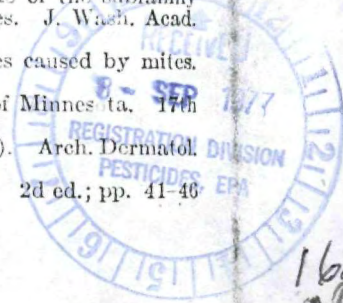
papules surrounded by an inflamed area. The papules may be surmounted by a pinhead-sized vesicle containing clear fluid. The itching generally reaches its maximum on the second or third day, then gradually subsides, though it may persist intermittently for several weeks. Scratching may be followed by secondary infection. If the lesions are numerous, fever, headache, and temporary nervous upset may result, and the intense pruritus may lead to loss of sleep and digestive disturbances. In this country chiggers are not known to transmit any disease, but in the Orient an allied species has been shown to be the carrier of pseudotyphus or Japanese river fever.

Treatment and prevention.—If it is known that there has been exposure to chiggers the skin should be examined, preferably with a hand lens, for the active larvae. However, they are so minute and they move so rapidly over the surface of the skin before attachment that it is difficult to capture them. An application of kerosene or 95 percent alcohol will kill the larvae quite rapidly. As soon as possible after exposure, it is advantageous to apply a thick lather of soap to the affected parts, allowing it to remain for 10 minutes or more before bathing. Even though the larvae may be removed or killed soon after attachment, usually enough secretion has been introduced into the skin to cause the characteristic itching lesion, and for this there is no known specific remedy. The intense itching may be temporarily relieved by ammonia or strong salt water, or a calomel phenol lotion. Collodion with metaphen applied to the lesions is recommended both to relieve the itching and to prevent infection.

In the summer and early fall when it is necessary to go into fields of tall weeds or grass, into berry patches, or wherever there is heavy undergrowth, an efficacious measure to prevent attack by chiggers is the liberal sprinkling of the stockings and underclothing with flowers of sulfur. Some authors have stated that the spraying of the shoes, stockings, and trouser legs with one of the proprietary fly-repellant preparations is successful in warding off attacks by chiggers.

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Fig. 204. Liponyssus bacoti. Greatly enlarged. (Ewing's External Parasites, courtesy of Charles C. Thomas.)

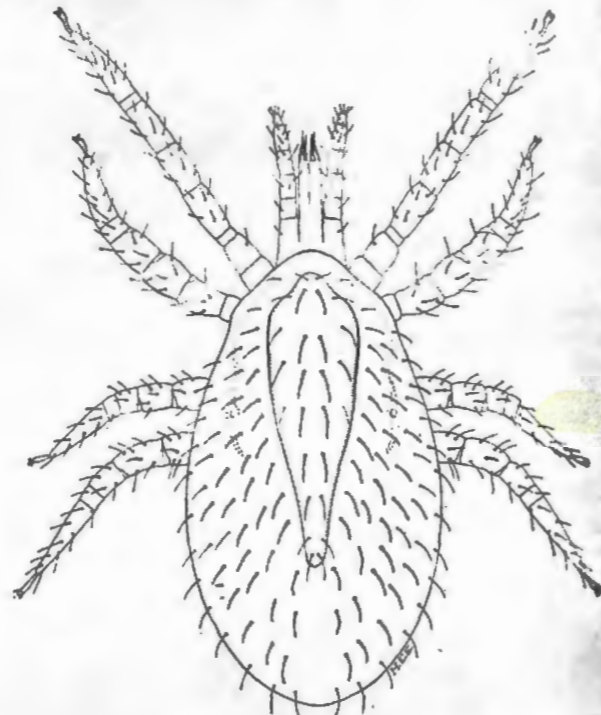


Fig. 204.—*Liponyssus bacoti*. Greatly enlarged. (Ewing's External Parasites, courtesy of Charles C. Thomas.)

IX. PREDACEOUS MITES (TARSONEMOIDEA)

Some of the species of this group are predaceous on insects that attack grain crops. Of particular interest, both biologically and medically, is *Pediculoides ventricosus*, the grain itch mite, which feeds on the larvae of several insects infesting seeds, grain, and plant stems. The young female is elongate-pyriform in shape. After fertilization the eggs are retained in her abdomen, where they develop into mature mites before they are deposited. During this period of "pregnancy" the abdomen of the female becomes tremendously inflated like a balloon, to accommodate the progeny, which may number up to 200 or 300. Optimum development of this mite apparently takes place at about 28° C. There is a cyclical reproduction about every four months, according to new broods of graminivorous insects on which it feeds. Persons in contact with grains or straw harboring these mites, particularly threshing crews, or persons sleeping on unfertilized

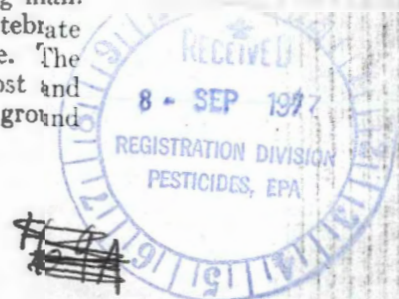
into the epidermis and produce petechial hemorrhage and later, later followed by a wheal, vesicle and pustule at each site. At times practically covering the whole body. The lesions are accompanied by a very annoying burning pruritus, at times accompanied by elevation of temperature and sweating. In 1928, Ciarrocchi reported a severe epidemic of this mite in Italy. It is very common in Bulgaria and in southeastern Bulgaria, where it infests dwellings where cereals are stored. It is also widely distributed throughout the wheat belt of South Australia. In Egypt the organism is found on the pink boll-weevil; in India, Algeria, Europe and North America in association with wheat, rye and barley straw. Application of warm water and mild antiseptics should be placed locally on areas involved. Little or no immunity is developed to this mite. Persons may become reinfested several times during the same season. The most helpful preventive measure would consist in the cleaning of granaries infested with the insects on which the mite feeds.

X. HARVEST MITES, CHIGGERS, "RED BUGS" (TROMBIDOIDEA)

Phylogenetic and Biological Data.—Of the six families of the Trombidoidea, mites which are characterized by having the spiracular openings of the tracheate system opening at the side of the beak (sternalum), only the type family Trombidiidae has species of medical interest. These are the harvest mites (chiggers, "red bugs," *Montanogamushi* or *Kedani* mite of Japan), various species of which have an extensive distribution throughout the world. Most species have a reddish color, or are spotted with red, orange or black. The nymphs and adults are either predaceous on other insects, the juices of which they extract, or are wholly vegetable feeders. Only the 6-legged larvae are blood-suckers. The adults may reach a length of 1.25 mm. but most of them are smaller, and are completely clothed with hairs, those of the body having multiple barbs in some species. (Fig. 205.) The cephalothorax bearing the mouth parts and the anterior 2 pairs of legs, is usually separated from the abdomen by a constriction. The series of only three species are fully known (*Trombidium* [syn. *T. alfreddugesi*] of North America, *T. autumnale* of Europe and *T. akamushi* of Japan). Eggs are laid and hatch on the ground. The emerging 6-legged larvae (Fig. 206) usually crawl on small rodents, but may attack birds, snakes, toads and turtles, and mammals such as rabbits, or other mammals, including man. Some species attack insects, particularly flies. On smaller vertebrates, the ears are a favorite locality for these larvae. The mouth and chelicerae are sunk into the skin of the host and blood meal is taken. The larvae then drop to the ground.

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and transform into nymphs. After one or two moults the nymph develops and the life cycle is repeated. In the United States *T. irritans* is prevalent on grass and bushes, particularly blackberry bushes, throughout the late spring and summer. It is most common in the Southern States, its distribution extending as north as Minnesota and New York. Ewing (1920) believed the species to be identical with *T. thalassius* of Mexico. In Europe *T. autumnale* larvae are common pests in the fall during the warm season.

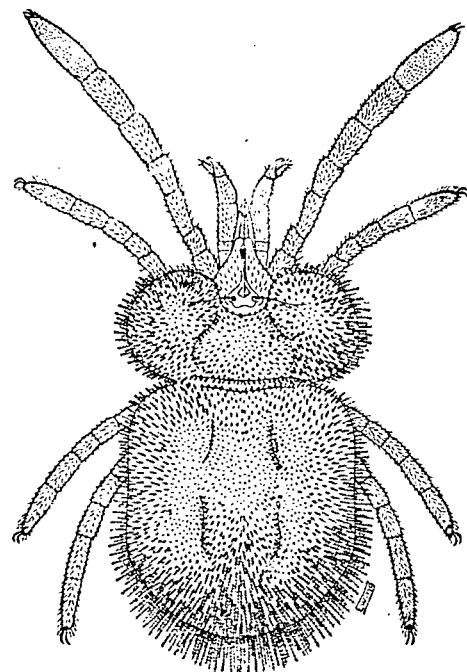


FIG. 203.—Adult *Trombidium irritans* (American "red bug"). (Ewing's External Parasites; courtesy of Charles C Thomas.)

Medical Importance of Trombidium.—**Dermatitis.**—The *Trombidium* which attack man in order to obtain a blood meal attach themselves to the skin by their mouth parts and inject salivary juices, the combination of which causes a marked allergic reaction which usually does not appear until twelve to twenty-four hours after attachment. The lesion first appears as a minute elevation on the skin, accompanied by intense painful pruritus. Soon a wheal develops around the site, frequently with extravasation of blood. Usually the skin becomes excoriated as a result of scratching, with serous exudation, and frequently a pustule develops at the site, probably due to bacteria introduced into the wound by the mite. Some persons are much more sensitive to these

others, and the lesions may remain painful for a week or more. The regions most commonly attacked are the ankles and external genitalia, groin and waistline, but the mites may also attack the axilla or the breasts. Once attached to the skin, the mites are individually removed by using a sharp needle, but the dermatitis is not measurably affected by this procedure. Hot camphor solutions in pure mineral oil applied locally are probably as palliative as any medicament. Flowers of sulphur in powder, dusted into the clothing before exposure, is recommended as a prophylactic.

Transmission of Disease.—In Japan, Formosa, the Pescadore, Federated Malay States, Sumatra, Samoa, and possibly in French Indo-China, the Philippines and South Australia, a number of species of *Trombidium* are transmitters to man of an

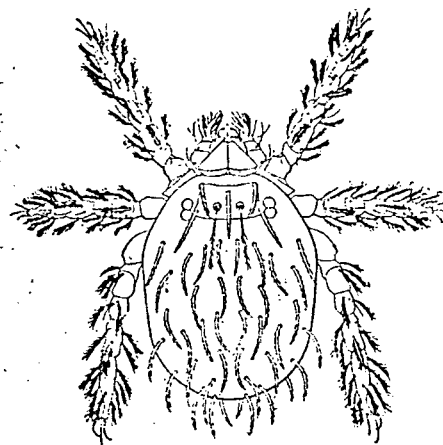


FIG. 204.—*Trombidium akamushi* larva. Greatly enlarged. (Nagayo et al., Am. Jour. Hyg.)

ant infection of rickettsial origin (*Rickettsia orientalis* Nagayo, which in Japan is referred to as "river fever" or "tsutsu-gamushi" (tsutsugamushi is the Japanese name for a mite), also as "pseudo-typhus," and in the Federated Malay States as "scrub typhus." The virus in Japan is commonly present in mice, rats and voles, particularly the vole, *Microtus monivittatus*, from which the larval mites get the infection during a blood meal of two to four days' duration, usually taken from the ear. The mites then drop off, transform successively into nymphs and adults, the latter mating and the females laying eggs. The virus is transmitted from the larva of one generation to that of the next (the period of about thirty days). When human beings are bitten by infected second generation mites, they acquire the infection. In other endemic foci in the Orient varieties of the black

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line 1 (volume) may be satisfactorily substituted (Switzer and 1935). Irrespective of the specific parasiticide, the patient is first thoroughly scrubbed all over with green soap, with a bath of warm water to expose the lesions, and then dried. The surface of the body, but especially the sites where the lesions are most conspicuous, are next thoroughly rubbed with the ointment. This is left on overnight. In the morning freshly sterilized clothing is put on and all soiled clothing and bed linen are boiled. In most cases one application will kill all the motile forms but will not kill the unhatched eggs, which must be attacked after they have hatched by a second application of the ointment between the sixth and eighth days following the first application. In patients with extensive involvement of the skin it is probably advisable to repeat treatment each night for six successive times. For small children with sensitive skin, it may be necessary to dilute the ointment one-half with an inert base.

Prevention.—Sarcoptic itch or mange is most common in jails and other groups, such as isolated families, where personal hygiene is neglected. While it is possible that cases occasionally acquire the infestation from domestic animals, practically all patients become infested from contact with other human beings, their clothing or bed linen. All cases should be given prompt treatment and their clothing thoroughly sterilized by boiling.

Other Sarcoptoid Mites Infesting Man.—Species of *Tyroglyphus* (*T. longior* and *T. siro*), which feed on cheeses and cereals, and *Ciphagus domesticus*, which feeds on all sorts of organic matter, and *Alcurobius farinæ*, which feeds on cereals and cheeses, all get on the hands, migrate under microscopic scales of the outer layer of the skin, or into cracks of the epidermis, and produce temporary pruritus. Washing the affected members thoroughly with kerosene-soapsuds should remove and kill these organisms, which are not known to suck blood. Occasionally these mites are swallowed in food and are discovered in the microscopic examination of the feces. While they may become lodged for a brief time in the intestinal crypts and may produce temporary irritation of the bowel, with a transient diarrhea, they are probably not adapted to permanent lodgment there (Hinman and Kanamitsu, 1931). Another member of this group, *Rhizoglyphus parvipes*, causes the "coolie itch" of the feet in tea plantations of India. It is a mite that a group of these mites invades the skin and produces sores on the soles of the feet, but it seems more likely that they invade already existing lesions.

VII. FOLLICULAR OR DEMODECTIC MITE (DEMODIOIDAE)

Demodex folliculorum (Fig. 203) parasitizes the hair follicles and sebaceous glands of man and domestic animals, where they live in shallow burrows, usually setting up a mild pruritus.

a fibrous tissue response around the offending organism. In man, but commonly in dogs and cats, the involved skin becomes raw, with extensive serous exudation. In 1901, Dubreilh and a co. of cutaneous pigmentation due to this mite. Paraut (1926) attributed to it the etiologic rôle in certain cases of senile keratosis and epithelioma. Interest in the rôle of the *Demodex* mite has been revived since 1930, when reported 11 cases of this infestation, the lesions were characterized by a dry erythema, with follicular scaling, and by burning sensations. These, together with 30 additional cases studied by Ayres anderson (1932), occurred most frequently due to use of face creams instead of face lotions. These clinicians have found the following to be of specific value in the treatment of mange: beta-naphthol, 4 cc.; sublimated sulphur, 8 cc.; balsam of Peru, 30 cc.; petrolatum, 30 cc.

PARASITOID MITES (PARASITOIDEA)

The species *Liponyssus bacoti* (Fig. 204) is the most common mite of warm climates and is common in the Southern United States. It feeds only on blood and drops off its host after each blood meal. Persons employed in granaries, food supplies, stockyards and other places frequented by rats are greatly annoyed and distressed by these organisms. Furthermore, Shelmire (1931) have shown that each mite takes at least 4 blood meals from larva to adult, and severe dermatitis, with urticarial papules and vesicles, develops at the site of the bite. In a severe case, a deep ulcer, a pressure sore, or a pressure wound, and that danger of secondary infection from scratching the lesion is increased by the mites, attacking human beings, especially children. These investigators have demonstrated experimentally that this mite is a reliable transmitter of endemic typhus. Several species of this genus (*L. bursa*, *L. nagayoi*, *L. turanicus*), as well as *Dermanyssus gallinæ*, which is a common parasite of fowls, readily attack man and produce an acute dermatitis. Yamada (1932) has demonstrated that *L. bacoti* is as dangerous as a vector of bubonic plague, and Morishita has found that *Liponyssus* is a fair incubator of relapsing fever. He has obtained from sucking on wild rats, but that this



FIG. 203.—*Demodex folliculorum*. Greatly enlarged. (After Faust, in Brennemann, Practice of Pediatrics, courtesy of W. F. Prior Company.)

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● **SENDER** Complete items 1, 2, and 3.

Add your address in the "RETURN TO" space on reverse.

1. The following service is requested (check one).

☒ Show to whom and date delivered..... 15¢☐ Show to whom, date, & address of delivery.. 35¢☐ **RESTRICTED DELIVERY.**

Show to whom and date delivered..... 65¢

☐ **RESTRICTED DELIVERY.**

Show to whom, date, and address of delivery 85¢

2. **ARTICLE ADDRESSED TO:**CHIGG-AWAY
E.P.A. File Symbol 36864-R3. **ARTICLE DESCRIPTION:**

REGISTERED NO.

CERTIFIED NO.

INSURED NO.

188562

(Always obtain signature of addressee or agent)

I have received the article described above.

SIGNATURE

☐

Addressee

☐

Authorized agent

4.

DATE OF DELIVERY

6-30-77

POSTMARK

5. **ADDRESS** (Complete only if requested)6. **UNABLE TO DELIVER BECAUSE:**CLERK'S
INITIALS

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IRB PM 15
Room 229

74A

27A

UNITED STATES POSTAL SERVICE
OFFICIAL BUSINESS

SENDER INSTRUCTIONS

Print your name, address, and ZIP Code in the space below.

- Complete items 1, 2, and 3 on the reverse.
- Moisten gummed ends and attach to front of article if space permits. Otherwise affix to back of article.
- Endorse article "Return Receipt Requested" adjacent to number.

PENALTY FOR PRIVATE
USE TO AVOID PAYMENT
OF POSTAGE \$300



**RETURN
TO**



Environmental Protection Agency
Office of Pesticides Programs,
Registration Division, WH-567
Washington, D.C. 20460

(Name of Sender)

(Street or P.O. Box)

(City, State, and ZIP Code)

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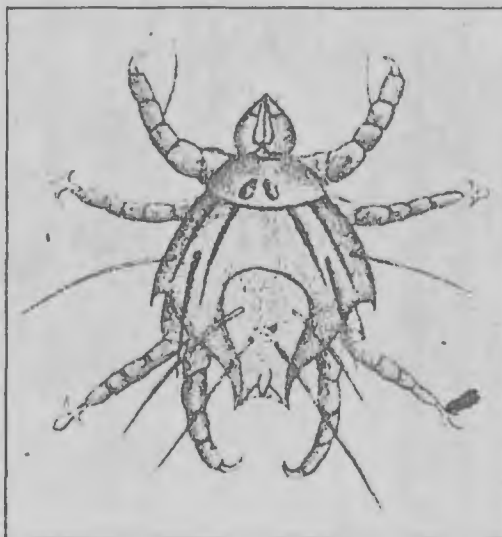
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There is a very striking sexual dimorphism in this species. The non-gravid female is elongate, about 200μ by 70μ (fig. 52), with the abdomen slightly striated longitudinally. The gravid female (fig. 53) has the abdomen enormously swollen, so that it is from twenty to a hundred times greater than the rest of the body. The species is viviparous and the larvæ undergo their entire growth in the body of the mother. They emerge as sexually mature males and females which soon pair. The male (fig. 54) is much smaller, reaching a

length of only 320μ but is relatively broad, 80μ , and angular. Its abdomen is very greatly reduced.

As far back as 1850 it was noted as causing serious outbreaks of peculiar dermatitis among men handling infested grain. For some time the true source of the difficulty was unknown and it was even believed that the grain had been poisoned. Webster has shown that in this country (and probably in Europe as well) its



54. *Pediculoides ventricosus*, male. After Braun.

attacks have been mistaken for those of the red bugs or "chiggers" (larval Trombiidæ). More recently a number of outbreaks of a mysterious "skin disease" were traced to the use of straw mattresses, which were found to be swarming with these almost microscopic forms which had turned their attentions to the occupants of the beds. Other cases cited were those of farmers running wheat through a fanning mill, and of thrashers engaged in feeding unthrashed grain into the cylinder of the machine.

The medical aspects of the question have been studied especially by Schamberg and Goldberger and from the latter's summary (1910) we derive the following data. Within two to sixteen hours after exposure, itching appears and in severe cases, especially where expo-

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sure is continued night after night by sleeping on an infested bed, the itching may become almost intolerable. Simultaneously, there appears an eruption which characteristically consists of wheals surrounded by a vesicle (fig. 55). The vesicle as a rule does not exceed a pin head in size but may become as large as a pea. Its contents



55. Lesions produced by the attacks of *Pediculoides ventricosus*. After Webster.

rapidly become turbid and in a few hours it is converted into a pustule. The eruption is most abundant on the trunk, slight on the face and extremities and almost absent on the feet and hands. In severe cases there may be constitutional disturbances marked, at the outset, by chilliness, nausea, and vomiting, followed for a few days by a slight elevation of temperature, with the appearance of albumin in the urine. In some cases the eruption may simulate that of chicken-pox or small-pox.

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Treatment for the purpose of killing the mites is hardly necessary as they attach feebly to the surface and are readily brushed off by friction of the clothes. "Antipruritic treatment is always called for; warm, mildly alkaline baths or some soothing ointment, such as zinc oxide will be found to fulfil this indication." Of course, reinfestation must be guarded against, by discarding, or thoroughly fumigating infested mattresses, or by avoiding other sources. Goldberger suggests that farm laborers who must work with infested wheat or straw might protect themselves by anointing the body freely with some bland oil or grease, followed by a change of clothes and bath as soon as their work is done. We are not aware of any experiments to determine the effect of flowers of sulphur, but their efficiency in the case of "red bugs" suggests that they are worth a trial against *Pediculoides*.

Various species of *Tyroglyphidæ* (fig. 150f) may abound on dried fruits and other products and attacking persons handling them, may cause a severe dermatitis, comparable to that described above for *Pediculoides ventricosus*. Many instances of their occurrence as such temporary ectoparasites are on record. Thus, workers who handle vanilla pods are subject to a severe dermatitis, known as vanillism, which is due to the attacks of *Tyroglyphus siro*, or a closely related species. The so-called "grocer's itch" is similarly caused by mites infesting various products. Castellani has shown that in Ceylon, workers employed in the copra mills, where dried cocoanut is ground up for export, are much annoyed by mites, which produce the so-called "copra itch." The skin of the hands, arms and legs, and sometimes of the whole body, except the face, is covered by fairly numerous, very pruriginous papules, often covered by small, bloody crusts due to scratching. The condition is readily mistaken for scabies. It is due to the attacks of *Tyroglyphus longior castellanii* which occur in enormous numbers in some samples of the copra.

Sarcoptidæ

The *Sarcoptidæ* are minute whitish mites, semi-globular in shape, with a delicate transversely striated cuticula. They lack eyes and tracheæ. The mouth-parts are fused at the base to form a cone which is usually designated as the head. The legs are short and stout, and composed of five segments. The tarsi may or may not possess a claw and may terminate in a pedunculated sucker, or simple long bristle, or both. The presence or absence of these structures

REPORT OF TELEPHONE CALL OR VISITOR			NOTE: Complete this form. Write "NA" where not applicable.
<input type="checkbox"/> INCOMING CALL	<input type="checkbox"/> VISITOR	DATE 8/19/77	
<input checked="" type="checkbox"/> OUTGOING CALL	<input type="checkbox"/> CONGRESSIONAL	TIME OF CALL 3:30	
NAME AND ADDRESS OF CALLER OR VISITOR Mr. James Bendure Pierson Labs., Inc. Leawood, KS		PHONE NO. (Include Area Code or IDS No.) (816) 753-4600 X 276	
		REGISTRATION, ID NO. OR FILE SYMBOL 36864-R	
		DATE OF LATEST SUBMISSION	
BRIEF SUMMARY OF CONVERSATION I called Bendure to inform him of what Tom Behan & I discussed 8/16/77 (see memo). Told him of additional efficacy requirements - copies of articles.			
ACTION TAKEN OR RECOMMENDED Bendure said articles would be OK, although he has additional data on tests which they <u>may</u> submit. (These tests used 150 students in VA) Bendure will submit one/both to cover efficacy requirements, but will need additional 75 days. -OK			
RECORDED BY (Name) JSE/Kabinger		REFERRED TO (Name)	

REPORT OF TELEPHONE CALL OR VISITOR			NOTE: Complete this form. Write "NA" where not applicable.
<input type="checkbox"/> INCOMING CALL	<input type="checkbox"/> VISITOR	DATE 8/16/77	
<input checked="" type="checkbox"/> OUTGOING CALL	<input type="checkbox"/> CONGRESSIONAL	TIME OF CALL 915	
NAME AND ADDRESS OF CALLER OR VISITOR Tom Behan Pierson Labs., Inc		PHONE NO. (Include Area Code or IDS No.) (804) 794-8507	
		REGISTRATION, ID NO. OR FILE SYMBOL 36864-R	
		DATE OF LATEST SUBMISSION	
BRIEF SUMMARY OF CONVERSATION I called to inform him of our conversation with Carl Schneck - efficacy researcher in Florida. I told Behan that Schneck told us (Phil Hutter) he felt confident of product's efficacy. I also explained our reviewer's requirements that they could only accept what was has information has been submitted to them.			
ACTION TAKEN OR RECOMMENDED I suggested that he ^(Behan) obtain a few more copies of military journal articles on sulfur/chigger research. He didn't think that would be a problem. I offered to call James Bendure - VP of Pierson Labs, to assure him of labeling requirements.			
RECORDED BY (Name) J. Ellinger		REFERRED TO (Name)	

IN	VISITOR	DATE 8/3/77 108
OUTGOING CALL	CONGRESSIONAL	TIME OF CALL 3:00
NAME AND ADDRESS OF CALLER OR VISITOR Carl Schneck IAMRL, USDA Gainesville, Florida		PHONE NO. (Include Area Code or IDS No.) (8) 947-7327
		REGISTRATION, ID NO. OR FILE SYMBOL 36864-R
		DATE OF LATEST SUBMISSION 7-21-77

Schneck said that the material was effective in these limited tests. We agreed, but informed him that these were the only tests submitted on this compound, and that we could not use any of the copious information on sulfur/chiggers in support of his registration unless it was submitted or referenced.

Mr. Schneck understood our position. The rest of the discussion concerned some experimental repellants in which we have a mutual interest.

Phil Hutton, Entomologist
EEEB 8/5/77.

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ENVIRONMENTAL PROTECTION AGENCY

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JUN 17 1977

Mr. James Bendure
 Pierson Laboratories, Inc.
 2304 West 105
 Leawood, KS 66206

Dear Mr. Bendure:

Subject: CHIGG-AWAY
 EPA File Symbol 36864-R
 Submission of May 2, 1977

This letter is in response to the material hand delivered to the Registration Division on May 2 by Mr. Thomas Behan of your company. We have reviewed the material in light of the requirements for registration and have attempted twice to meet with Mr. Behan to discuss this matter.

While much pertinent information was submitted on the product's chemistry and toxicology, enough to satisfy the toxicology data requirements, more information is needed on the product's chemistry and efficacy. Comments on these outstanding data requirements and other items of the application, including labeling, are listed below.

(1) The information submitted to support the product's general chemistry requirements is incomplete for several of the items we identified in previous correspondence. These items are:

(a) Source of chemical for each active ingredient. In your submission two supportive letters - [REDACTED]

[REDACTED] are included from suppliers of sulfur. We wish to know which one of these company's products you intend to use to formulate Chigg-Away. Be reminded that sulfur used to formulate your product must bear Federal registration.

(b) What are the complete compositions, including the impurities, of each active ingredient? This could be answered by having each supplier submit a confidential statement of formula for their product.

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CONCURRENCES

SYMBOL	WA-567	WA-567	WA-567					
SURNAME	Bendure	Bendure	Bendure					
DATE	6-14-77	6-14-77	6-16-77					

(c) Provide us with the analytical method(s) for the principle component and impurities in the technical benzocaine.

(d) Be more specific than "Spectrograph" in identifying the analytical method(s) for the active ingredients in the formulation.

(e) A statement that the product is stable for a minimum of five (5) years is insufficient. Stability data must be submitted which will support such a claim. Test protocol for storage stability is as follows:

1. Specify the method of Analysis. Show that this method is reproducible and accurate within 3%.

2. Include in a data table:

- a. Dates of Analyses
- b. Batch or Lot Number
- c. % active ingredient or data and calculations.

3. The product should be analyzed before storage, after 12 months, and several times during the 12 month period.

NOTE: We will accept accelerated stability data on an interim basis, i.e., storage at elevated temperature (50°C) with analysis before storage and after 30 days. The results of the 12 month storage stability test must be received by the Agency within two years after the granting of registration.

(f) In your confidential formula allowance must be made for the impurities [redacted] in the technical grade sulfur. [This was brought to your attention in our June 4, 1975 letter.]

used for accession no 286520

(2) In regard to the submitted efficacy studies, the test methods and results qualify the tests only as screening tests for biological activity of the formulation, and thus the studies will not fully support the efficacy data requirements for registration. Our objections to the methodology are as follows:

(a) Too few replicates, three, were used.

(b) The mite (chigger) population pressure was too low.

- (c) The compound was applied to the subject's arms instead of as directed on the product label.

Obviously then, tests should be performed using more replicates, the number being unfixed but sufficient to provide confidence in reproducible results; tests performed under high population pressure of mites to ensure the product's efficacy under these conditions; and, the compound is to be applied as directed on the label so data may be gathered from relevant sites on the subjects' bodies.

Good, applicable published data may be substituted for the above studies. We refer you to your previous, January 16, 1975, attempt at this. Unfortunately, the studies in the articles had too many unsimilarities to data protocol for your product that the studies could not be considered applicable.

(3) An obsolete Application for New Pesticide Product Registration (EPA Form 8570-1, Revised 11-74) was submitted in which two methods of support, 2A and 2B, were checked. As the original application, submitted August 27, 1975, had a checked method of support of 2B, indicating that some or all of the data would be referenced, the checking of 2A will be considered an unintentional error. In any event, a revised Offer to Pay Statement must be completed and returned. See the enclosure. Also please indicate only one method of support.

- (4) Make the following label changes:

- (a) The correct form of the ingredient statement is

ACTIVE INGREDIENTS

Name of ingredient %

Name of ingredient %

INERT INGREDIENTS %

The words, "ACTIVE INGREDIENT(S)" and "INERT INGREDIENT(S)", must be printed in type of the same size and color and be given equal prominence. The words "ACTIVE INGREDIENT(S)" and "INERT INGREDIENT(S)" must be aligned to the same margin.

It is preferred that the ingredient statement be placed on the front panel of the label.

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- (b) Provide a complete address on the label.
- (c) On the front panel "Keep Out of Reach of Children" must be above "Caution". Note the enclosure for correct type sizes of these two statements.
- (d) The precautions on the back panel must precede the directions and be headed with "Precautionary Statements", followed beneath by "Hazards to Humans", and followed beneath by the precautions.
- (e) After the precautionary section use the heading "Directions for Use", followed beneath with "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." Specific directions follow.
- (f) After the directions use the heading "Disposal" followed beneath by "Do not reuse empty container. Wrap container and put in trash collection." "Disposal" must be of type size equal to that as required for the child precautionary statement on the front panel.

(5) We also acknowledge that the formulation has been changed from 5.0% to 10.0% sulfur.

(6) If revised labeling, data or a written request for additional time is not submitted to the Registration Division within seventy-five (75) days of the date of this notice, the application will either be administratively withdrawn or denied pursuant to the provisions of 40 CFR section 162.7(e). — extended additional 75 days on 8/19/77

(7) This product is considered to be both a pesticide because of the repellancy claim, and a drug because of its intended effect to reduce itching. FDA/Bureau of Medicine does not consider it to be a "new drug". Therefore, this product as presently labeled will remain under the jurisdiction of both agencies.

and
10/11/77

Sincerely,

S/Douglas D. Campt

Douglas D. Campt
Acting Director
Registration Division (WH-567)

Enclosures

cc: Mr. Thomas Behan
11304 Dunkrook Road
Richmond, VA 23235

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WH-567:IRB:TAGarnder:cd:rm219:WEME:x68815:6/14/77

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REPORT OF TELEPHONE CALL OR VISITOR			NOTE: Complete this form. Write "NA" where not applicable.
INCOMING CALL		VISITOR <i>Meeting</i>	DATE <i>6-9-77</i>
OUTGOING CALL		CONGRESSIONAL	TIME OF CALL <i>pm</i>
NAME AND ADDRESS OF CALLER OR VISITOR <i>Phil Hutton Entomologist, EEE Branch</i>			PHONE NO. (Include Area Code or IDS No.)
			REGISTRATION, ID NO. OR FILE SYMBOL <i>36864-R</i>
			DATE OF LATEST SUBMISSION <i>5/2/77</i>
BRIEF SUMMARY OF CONVERSATION			
<p><i>Phil looked over the at efficacy data submitted to support product. He felt this is not supportive because of the methods:</i></p> <ol style="list-style-type: none"><i>1. The test was only a screening test to show biological activity of compound.</i>			
ACTION TAKEN OR RECOMMENDED			
<ol style="list-style-type: none"><i>2. Too few replicates (3) were used.</i><i>3. mite (chigger) population pressure too low.</i><i>4. Compound in test applied to arms instead as directed in label directions.</i> <p><i>Data should be gathered from tests utilizing the product as directed on the label, with adequate replicates, and to ^{under} high, chigger, population pressure.</i></p>			
RECORDED BY (Name) <i>R. S. H. H. H. H. H.</i>		REFERRED TO (Name)	

CHIGG-AWAY

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FRONT PANEL

NEW

Fights Chiggers 2 ways!

CHIGG - A W A Y

1. REPELS Chiggers!
2. RELIEVES itching of Chigger bites!

Caution: Keep out of reach of children. See back panel for further cautions and directions.

4 Fluid Ounces

BACK PANEL

CHIGG-AWAY

For External Use Only- Do Not Take Internally

Works Two Ways -

1. Effectively repels chiggers! Apply around ankles, waist and to skin under all areas of tight fitting clothing and around all openings in outer clothing. Re-apply after heavy exercise or swimming.
2. Relieves itching and discomfort of bites from chiggers, mosquitoes, ticks and biting flies. The unique action of Chigg-Away Lotion carries prompt relief to the source of irritation. Provides soothing relief from itching. Apply topically and rub in well as needed.

Caution: Keep away from eyes or other mucous membranes. Not for prolonged use. If the condition for which this preparation is used persists or if a rash or irritation develops, discontinue use and consult physician.

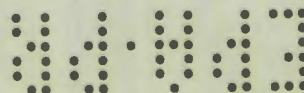
Caution: Not to be used in infants younger than two years because of risk of methemoglobinemia.

Active Ingredients:

Precipitated Sulfur 10%
Benzocaine 0.5%

© 1976 Pierson Laboratories, Inc.
P.O. Box
Lenexa, Kansas

EPA Reg. No.
EPA Est. No.



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241

1. Like double-headed arrow with two-way action. - Man.
 2. MAN

NOW RELIEF FROM
CHIGGERS

**CHIGG
 AWAY**

TWO-WAY ACTION

1. REPELS CHIGGERS
 2. Relieves itching

Net wt.
 0.02.

BEST DOCUMENT AVAILABLE

23 9

84 843



BEST DOCUMENT AVAILABLE

227 4

88883

#1 mat

11

117

NOW! RELIEF FROM
CHIGGERS

**CHIGG
AWAY**

TWO-WAY ACTION

REPELS CHIGGERS	RELIEVES ITCHING
--------------------	---------------------

~~Not to be used~~

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227 4

00003

244

94

90

76

1. Number one choice - likes red cross - Marv
#7 Marv



BEST DOCUMENT AVAILABLE

227 4

88843

1. Easy to read, - Man

**NOW RELIEF FROM
CHIGGERS**

CHIGG AWAY

**TWO WAY
ACTION...**

- ① REPELS CHIGGERS**
- ② Relieves itching**

===== **WATER
TIGHT**

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22.3 9

84.843

2 Man...

II 2

120



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227 4

88843

Product ingredient source information may be entitled to confidential treatment

() The items on the General Chemistry requirements checklist that still need to be satisfied are 2-03, 2-20, 2-21, 2-26, and 2-38. An elaboration on these items follows

2-03

Your submission of 5/2/77 includes a letter from General Scientific stating that they will supply you with sulfur and a copy of a letter of authorization from [REDACTED] on their product [REDACTED]

Please clarify which of these products you are using. You are reminded that the sulfur used to formulate your product must be registered with EPA.

JP 98

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- 2-20 This item can be satisfied by having each of your suppliers submit a confidential statement of formula on their product
- 2-21 ~~A method~~ no explanation necessary
- 2-26 Be more specific than "Spectograph"
- 2-38 A statement that the product is stable for a minimum of five years is not acceptable. We must have the actual data. A copy of the protocol is attached
- () T-1, T-2, T-3, T-88, T-89
- () Comment 2 of our letter of June 4, 1975 still apply. We do not know of any sulfur product that is 100% sulfur.

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EPA #	Date	Product Name	Use Classification	Toxicity Category
36864-R	5/2/77	Chigg-Away	General	122 III

RECOMMENDATION: ☒ register ☐ other (explain)

We recommend the registration of the product. The requirement for subacute dermal, skin sensitization and teratology studies ^{should} ~~can~~ be exempted for the following reasons: see attached.

Acute Oral (Rat)	LD50	TECH	FORMULATION	USE DILUTION	DATA ACCEPTABLE
		—	> 4 gm/kg	—	yes

Toxic signs: None

Comments: Acceptable because of low toxicity

Tox. Cat. IV

Acute Dermal (Rabbit)	LD50	—	> 9.0 gm/kg	—	yes
-----------------------	------	---	-------------	---	-----

Toxic signs: None

Comments: Acceptable because of low toxicity

Tox. Cat. III

Acute Inhalation ()	LC50	—	Not Req'd.	—	—
----------------------	------	---	------------	---	---

Toxic signs:

Comments: Study is not required

Primary Eye Irritation (Rabbit) Draize score:	—	No irritation	Yes
---	---	---------------	-----

Comments: Study is accepted on low toxicity

Tox. Cat. IV

Primary Skin Irritation (Rabbit) Draize score:	—	No irritation	Yes
--	---	---------------	-----

Comments: No irritation on intact or abraded skin

Acceptable

Tox. Cat. IV

Other Studies:

Benzocaine ; acute oral LD50 = 1765 mg/kg (rats)

[REDACTED]

Sulphur acute oral LD50 = > 3000 mg/kg (rats)

These studies are not required:

Inert ingredient information may be entitled to confidential treatment

Date: 5/2/77

Subject: 36864-R, Chigg-Away Registration

To: Mr GEE, F.D.R., PM.

From: Dr. Chan S.L. Tox. branch.

Re

Recommendation cont'd:

The two active ingredients in the formulation are sulphur, 10% and Benzocaine, 0.5%, both of which have been widely used with proven safety with sulphur as a pesticide and benzocaine, a local anesthetic drug.

In addition, there is a decent body of evidence from scientific studies showing the relative safety for the repeated dermal (and other) applications of sulphur. A concentration of 10% or lower of sulphur is generally accepted as safe for topical applications.

Similar evidence is available for the drug, benzocaine.

The control of the use of (including repeated dermal applications) of benzocaine is largely the responsibility of the FDA. Benzocaine is mainly an OTC drug and is currently included in a review by the FDA advisory panel. Unless serious questions are raised in that review to be made available in the near future, we will have no objection for its inclusion in Chigg-Away.

Lastly, all the inerts and contaminants of the technical sulphur used in the formulation are acceptable.

Subject: Chigg Away

Subject: Chronology of Events in attempts to Register 36864-R, - Product Name, Chigg Away

From: PM-15

~~TH~~

To: Acting Associate Director
For Registration

Thru: Acting Branch chief, DRR

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Chigg
Hway
Chigg

36864-R 126
5-3-78

Chronology of Events

- ① application first received 4-7-75
- ② response (objection) sent by ^{Jerry} ~~Frank~~ Haurison 6-4-75
- ③ note received 4-14-75 changing company address and company name from S.L. Chigg Laboratories to Patterson Chemical
- ④ phone call from Tom ^{Behan} ~~Behan~~ 12-10-75 ^{complaining} ~~complain~~ that we lost jacket - . We did not lose the jacket, they had changed the company name again, moved again, changed company officers and did not leave ~~address~~
- ⑤ ^{Behan} ~~Behan~~ called Herb Haurison about mid December asking ~~what~~ ^{what} is required for registration
- ⑥ ^{Behan} ~~Behan~~ called Frank Sanders, apparently the next day - same as above (Frank was acting Branch Chief) also changed phone numbers
- ⑦ Mid December 1975 jacket transferred from PM-17 to PM-15 because of ^{joint} ~~joint~~ ^{jurisdiction} ~~jurisdiction~~ with FDA

⑧ received material from FDA in accordance with
the agreement with FDA ^{and} ~~material~~ ^{an} ~~on~~
~~the agreement~~ dated letter from ^{Behan} ~~Bell~~
on 12-16-75 again changing
company name and address.

Note: in eight months they have had three ~~company~~ names:

3L drug Co

Patterson Sabatini

Prison Sabotage

and at least four address changes

Kansas City (Blaine St)

Kansas City (and so)

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Seneca
~~Seneca~~ Kansas

~~Merion~~
~~Merion~~ Kansas

and several company officers, charged

⑨ included in the above submission ^{is} a
perox copy of a note from ~~Richard~~^P Heller
of FDA to Mrs. Underwood (?) returning
Chicago's FDA application - apparently
they sent the wrong forms to FDA and
furthermore, sent them to an FDA field
office in Kansas City.

Note: Robert Heller ^{is} ~~in~~ our FDA contact ^{in Rockville} ~~in Rockville~~ **255**

(10) also included in the 12-16-75 letter was a letter from Bob Heller to Timothy Sandeen discussing joint jurisdiction, over the counter drug reviews, and Federal Register publication.

Note: the letter seems to approve ^{continued} ~~continued~~ ^{marketing} ~~marketing~~ provided the company complies with EPA requirements. Also, FDA comments that they have never seen benzocaine used at the extremely low level of 0.05 %

Note: The FDA letter also indicates that Chris Lwiza will not be ^{producing} ~~producing~~ the ^{product} ~~product~~, but a fifth company ^{is} ~~is~~ now involved; ~~the~~ Adept Manufacturing in Brookfield, Missouri.

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- ⑪ December 23, 1975 we respond to receipt of the FDA material with a long letter (3 pages) outlining the FDA requirements and including a checklist of FDA requirements.
- ⑫ The company has apparently been in constant contact with our Kansas City Regional office - a Mr. Joe Poskin - This has added to the confusion regarding data requirements.
- ⑬ Kansas City Regional Administrator calls Ed Johnson ^(about 1-7-76). Ed calls John Ritsch, John calls me complaining about not receiving our letter. Mr. Ritsch responds to Ed Johnson, and I would inquire Ed's to Kansas City addressed all the company name changes - and address changes.

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- (14) January 16, 1976 memo to ~~file~~ file explaining the OTC Drug review panel

Note: "In essence FDA has not approved Chiggleway, but it has not objected either." ... "FDA sees no imminent hazard at this time"

Robert Helly FDA

- (15) January 16, 1976 Behan came in to discuss the same problems - also brought xerox copy of an article on the efficacy of sulfur

Note: this is not data but is the first attempt at compliance

- (16) letter dated July 14, 1976 hand carried in here by Behan on August 24, 1976 asking for confirmation of data requirements

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6881579

- (17) October 1, 1976 we sent letter including a revised checklist deleting several chemistry data and adding a few tox data requirements. Both of these changes are the result of known but unpublished changes in the guidelines.
- (18) October 6, 1976 Behar called with get another change of address -
Richmond Virginia
- (19) May 2, 1977 Behar hand carried a new submission in to Doug Empt. This submission will be discussed in detail -

Note: another address change to

Seewood Kansas

~~Chugley~~
 Latest
 ^

36864-R

Submission dated 5-2-77

I Forms

- ① generally OK to process
- ② his method of support is checked as A and B
- ③ there don't seem to be any lists of references - and, very little hard data (a page or two)

II Sabel

- ① Six different label front panels - none in compliance with Section 3 regulations (not even an ingredient statement)
- ② no back panels (i.e. no claims or directions, precautions etc.)

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III Data

see the attached data checklist
(this was sent with our letter
of October 1, 1976)

① Chemistry

there are ~~40~~ references needed

Behan has answered 10 and
taken a stab at 5

of the remaining 25 he
said "N/A" to six of
our checked requirements
for no apparent reason

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of the 10 he answered
and the ~~5~~ 5 he took
a stab at these were
all simply peroxis of
the March Index etc...
no real answers on
any of the questions on 82
the formulated product 10%

③ Environmental Chemistry

none required

④ Efficacy

Jaundice → repels chiggers
→ relieves itching

one test was submitted most
of it not relevant ie clothing
tests, cloth patch screen, etc.

However, there was one test that
did apply -

³ ~~men~~ men, one arm treated
one arm not treated -
exposed for one hour

⑤ Phytotoxicity

none required

⑤ Toxicology

there are 20 references needed

Behar has supplied very crude tests on the formulated product:

(7-7) primary skin irritation - apparently used two rabbits (maybe 3) in an unsigned, incomplete test that fails to identify who did the testing, analysis of the compound tested, etc. and not done in accordance with the proposed guidelines

(7-9) acute primary eye irritation same as above, but apparently three rabbits - not signed not identified etc. - also, rabbit numbers seem to have been changed. The report indicates no irritation; however, our toxicologists all thought there would be some because of the benzoin

(7-2) Acute oral - this was the only submitted test that was on the right track - I would call what was done "range finding" but not carried out to the point of establishing an LD50 except in the case of benzene, and then only marginally.

the remaining 17 tests were ignored

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GENERAL CHEMISTRY
REQUIREMENTS CHECKLIST

REGISTRATION NO. _____
DATE SUBMITTED _____

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* 2-01	Basic Manufacturing Process (for each active ingredient) [162.78(a)]	S R W N/A O	* 2-10	Boiling Point (for each active ingredient) [162.78(b)(3)(vi)]	S R W N/A O	* 2-19	Odor (for each active ingredient) [162.78(b)(4)(xv)]	S R W N/A O
* 2-02	Purity of Starting and Intermediate Materials Used in Manufacturing Process (for each active ingredient) [162.78(a)]	S R W N/A O	* 2-11	Vapor Pressure (for each active ingredient) [162.78(b)(3)(vii)]	S R W N/A O	2-20	Complete Composition Including Impurities (for each active ingredient) [162.78(b)(4)(xvi)]	S R W N/A O
* 2-03	Source of Chemical (for each active ingredient) [162.78(a)]	S R W N/A O	* 2-12	Density/Specific Gravity (for each active ingredient) [162.78(b)(3)(viii)]	S R W N/A O	* 2-21	Analytical Methods for Principle Component(s) and Impurities in Technical Chemical for each active ingredient (162.78(c)(2))	S R W N/A O
* 2-04	Quality Control Procedures Description (for each active ingredient) [162.78(a)]	S R W N/A O	* 2-13	Hydrolysis Rate (for each active ingredient) [162.78(b)(3)(ix)]	S R W N/A O	2-22	2-Gran Sample Purified Analytical Standard (for each active ingredient) [162.78(c)(2)]	S R W N/A O
2-05	Common Name (for each active ingredient) [162.78(b)(4)(i)]	S R W N/A O	* 2-14	Solubility in Various Solvents (for each active ingredient) [162.78(b)(3)(x)]	S R W N/A O	* 2-23	10 to 20-Gran Sample Batch Chemical (for each active ingredient) [162.78(c)(2)]	S R W N/A O
2-06	Chemical Abstracts Name (for each active ingredient) [162.78(b)(4)(ii)]	S R W N/A O	* 2-15	Dissociation Constants (for each active ingredient) [162.78(b)(3)(xi)]	S R W N/A O	2-24	Complete Chemical Composition - Confidential Statement of Formula (formulated product) [162.78(b)]	S R W N/A O
2-07	Trade Name (for each active ingredient) [162.78(b)(4)(iii)]	S R W N/A O	* 2-16	Stability (for each active ingredient) [162.78(b)(3)(xii)]	S R W N/A O	2-25	Basic Manufacturing Process (formulated product) [162.78(b)(3)(i)(2)]	S R W N/A O
* 2-08	Structural Formula (for each active ingredient) [162.78(b)(4)(iv)]	S R W N/A O	* 2-17	Physical State (for each active ingredient) [162.78(b)(3)(xiii)]	S R W N/A O	* 2-26	Analytical Methods for Active Ingredients in Formulation [162.78(b)(3)(i)(B)(3)]	S R W N/A O
* 2-09	Melting Point (for each active ingredient) [162.78(b)(3)(v)]	S R W N/A O	* 2-18	Color (for each active ingredient) [162.78(b)(3)(xiv)]	S R W N/A O	* 2-27	Miscibility in Various Solvents (formulated product) [162.78(d)(1)]	S R W N/A O

86
110

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GENERAL CHEMISTRY
REQUIREMENTS CHECKLIST

REGISTRATION NO. _____
DATE SUBMITTED _____

2-28	pH (formulated product) [162.78(d)(3)]	S R N /A O	2-37 * Weight Active Ingredient(s) per gallon (formulated product) [162.78(d)(6)]	S R N /A O		
2-29 *	Boiling Point (formulated product) [162.78(d)(2)]	S R N /A O	2-38 Storage Stability (formulated product) [162.78(e)]	S R N /A O		
2-30 *	Flashpoint (formulated product) [162.78(d)(2)]	S R N /A O	2-39 Total Tobacco/Smoke Residue Profile (for each active ingredient) [162.78(f)(1)]	S R N /A O		
2-31	Specific Gravity (formulated product) 162.78(d)(2)	S R N /A O	2-40 Follow-up Crop Tobacco Study [162.78(f)(2)]	S R N /A O		
2-32 *	Viscosity (formulated Product) [162.78(d)(2)]	S R N /A O				
2-33 *	Vapor Pressure (formulated Product) [162.78(d)(2)]	S R N /A O				
2-34 *	Explosive Characteristics (formulated product) [162.78(d)(3)]	S R N /A O				
2-35 *	Corrosion Hazards (formulated product) [162.78(d)(4)]	S R N /A O				
2-36 *	Oxidizing/reducing agent capability (formulated product) [162.78(d)(5)]	S R N /A O				

87
H

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TOXICOLOGY DATA
REGISTRATION FORM

PRODUCTION NO.
DATE RECEIVED

7-0	Acute Oral LD ₅₀ (rat - for each active ingredient) [162.81(b)(3)(1)]	S R W NA O	7-10	Acute Inhalation LC ₅₀ (rat - for each active ingredient) [162.81(b)(4)(1)(A)]	S R W NA O	7-19	Dermal Sensitization (guinea pig - formulated product) [162.81(b)(4)(1)(A)]	S R W NA O
7-2	Acute Oral LD ₅₀ (rat - formulated product) [162.81(b)(3)(1)]	S R W NA O	7-11	Acute Inhalation LC ₅₀ (rat - formulated product) [162.81(b)(4)(1)(A)]	S R W NA O	7-20	Dermal Photosensitization (guinea pig - for each active ingredient) [162.81(b)(4)(1)(A)]	S R W NA O
7-3	Acute Oral LD ₅₀ (rabbit - for each domestic use dilution) [162.81(b)(3)(1)]	S R W NA O	7-12	Acute Intraperitoneal (rat - for each active ingredient) [162.81(b)(4)(1)(B)]	S R W NA O	7-21	Dermal Photosensitization (guinea pig - formulated product) [162.81(b)(4)(1)(A)]	S R W NA O
* 7-4	Acute Dermal LD ₅₀ (rabbit - for each active ingredient) [162.81(b)(3)(1)]	S P W NA O	7-13	Acute Intraperitoneal (rat - formulated product) [162.81(b)(4)(1)(B)]	S R W NA O	7-22	Subacute Inhalation (rat - formulated product) [162.81(b)(4)(1)(B)]	S R W NA O
7-5	Acute Dermal LD ₅₀ (rabbit - formulated product) [162.81(b)(3)(1)]	S R W NA O	7-14	Acute Intravenous (rat - for each active ingredient) [162.81(b)(4)(1)(B)]	S R W NA O	7-23	Subacute Oral (Non-rodent mammal other than rabbit - for each active ingredient) [162.81(b)(4)(1)(C)]	S R W NA O
* 7-6	Acute Primary Dermal Irritation (rabbit - for each active ingredient) [162.81(b)(3)(1)]	S R W NA O	7-15	Acute Intravenous (rat - formulated product) [162.81(b)(4)(1)(B)]	S R W NA O	7-24	Subacute Oral (Mammal other than rabbit - for each active ingredient) [162.81(b)(4)(1)(C)]	S R W NA O
7-7	Acute Primary Dermal Irritation (rabbit - formulated product) [162.81(b)(3)(1)]	S R W NA O	7-16	Subacute Dermal (rabbit - for each active ingredient) [162.81(b)(4)(1)(A)]	S R W NA O	7-25	Teratology (mammal with hemochorial placenta - for each active ingredient) [162.81(b)(4)(1)(D)]	S R W NA O
* 7-8	Acute Primary Eye Irritation (rabbit - for each active ingredient) [162.81(b)(3)(1)]	S R W NA O	7-17	Subacute Dermal (rabbit - formulated product) [162.81(b)(4)(1)(A)]	S R W NA O	7-26	Neurotoxicity (adult hen - for each active ingredient) [162.81(b)(4)(1)(E)]	S R W NA O
7-9	Acute Primary Eye Irritation (rabbit - formulated product) [162.81(b)(3)(1)]	S R W NA O	7-18	Dermal Sensitization (guinea pig - for each active ingredient) [162.81(b)(4)(1)(A)]	S R W NA O	7-27	Neurotoxicity (rat or dog - for each active ingredient) [162.81(b)(4)(1)(F)]	S R W NA O

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REGISTRATION NO. _____
DATE EXPIRED _____

7-28	Metabolism (rat or dog - for each active ingredient) [162.81(b)(4)(1)(F)]	S R W NA O	7-36	Mutagenicity - <u>in vivo</u> cytogenetic test (rat or mouse - for each active ingredient) [162.81(b)(4)(1)(A)]	S R W NA O		
7-29	Metabolism (other species depending on use pattern - for each active ingredient) [162.81(b)(4)(1)(F)]	S R W NA O	7-37	Mutagenicity - specific locus test (mouse - for each active ingredient) [162.81(b)(4)(1)(A)]	S R W NA O		
7-30	Oncogenicity (rat - for each active ingredient) [162.81(b)(4)(1)(A)]	S R W NA O	7-38	Potentiation (for each active ingredient) [162.81(b)(4)(1)(3)]	S R W NA O		
7-31	Oncogenicity (most-sensitive mammalian species other than rat - for each active ingredient) [162.81(b)(4)(1)(A)]	S R W NA O	7-39	Re-entry (formulated product) [162.81(b)(4)(1)(C)]	S R W NA O		
7-32	Chronic feeding (rat - for each active ingredient) [162.81(b)(4)(1)(B)]	S R W NA O	7-40	Diagnostic Information [162.81(b)(4)(1)(C)]	S R W NA O		
7-33	Chronic Feeding (other species as determined by Reg.Div. - for each active ingredient) [162.81(b)(4)(1)(B)]	S R W NA O	7-41	First-aid information [162.81(b)(4)(1)(C)]	S R W NA O		
7-34	Reproduction (same rodent as chronic feeding study - for each active ingredient) [162.81(b)(4)(1)(C)]	S R W NA O	7-42	Palliative Information [162.81(b)(4)(1)(C)]	S R W NA O		
7-35	Mutagenicity - heritable translocation test (mouse - for each active ingredient) [162.81(b)(4)(1)(A)]	S R W NA O	7-43	Antidotal Information [162.81(b)(4)(1)(C)]	S R W NA O		

* 7-4 Human patch-test

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H3

53

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS (WH-567)
WASHINGTON, D.C. 20460

1. COMPANY/REGISTRATION NO.

2. EPA USE ONLY

LABEL TECHNICAL DATA

(See INSTRUCTIONS on back of last part)

3. PRODUCT NAME

CHLIGG-AWAY

150

F

4. APPLICATION SITES (Check all that apply)		5. PEST TYPE (Check all that apply)		7. USER TYPE (Check all that apply)	
<input type="checkbox"/> 01 CROPS (Fruit)	<input type="checkbox"/> 01 ALGAE	<input type="checkbox"/> 01 UNSPECIFIED GENERAL USE			
<input type="checkbox"/> 02 CROPS (Vegetable)	<input type="checkbox"/> 02 AMPHIBIAN/REPTILE	<input type="checkbox"/> 02 UNSPECIFIED RESTRICTED USE			
<input type="checkbox"/> 03 CROPS (Field)	<input type="checkbox"/> 03 BACTERIA	<input checked="" type="checkbox"/> 03 HOMEOWNER USE			
<input type="checkbox"/> 04 CROPS (Spice)	<input type="checkbox"/> 04 BIRDS	<input type="checkbox"/> 04 JANITORIAL USE			
<input type="checkbox"/> 05 CROPS (Nut)	<input type="checkbox"/> 05 FISH	<input type="checkbox"/> 05 PEST CONTROL OPERATOR USE			
<input type="checkbox"/> 09 CROPS (Other)	<input type="checkbox"/> 06 FOULING ORGANISMS	<input type="checkbox"/> 06 COMMERCIAL APPLICATOR USE			
<input type="checkbox"/> 10 SOIL TREATMENT (No crop specified)	<input type="checkbox"/> 07 FUNGI	<input type="checkbox"/> 07 FARMER USE			
<input type="checkbox"/> 20 FOREST	<input checked="" type="checkbox"/> 08 INSECTS AND MITES	<input type="checkbox"/> 08 MEDICAL USE			
<input type="checkbox"/> 30 ORNAMENTALS	<input type="checkbox"/> 09 MAMMALS	<input type="checkbox"/> 09 VETERINARY USE			
<input type="checkbox"/> 40 TURF	<input type="checkbox"/> 10 NEMATODES	<input type="checkbox"/> 10 GOVERNMENT AGENCY USE			
<input type="checkbox"/> 50 STORED PRODUCTS TREATMENT	<input type="checkbox"/> 11 PLANTS	<input type="checkbox"/> 11 MANUFACTURING USE			
<input type="checkbox"/> 61 ANIMALS (Livestock)	<input type="checkbox"/> 12 RODENTS	8. FORMULATION (Check one only)			
<input type="checkbox"/> 62 ANIMALS (Dairy)	<input type="checkbox"/> 13 SLIME				
<input type="checkbox"/> 63 ANIMALS (Pet)	<input type="checkbox"/> 14 SLUGS AND SNAILS	<input type="checkbox"/> 01 TECHNICAL CHEMICAL			
<input type="checkbox"/> 64 ANIMALS (Laboratory)	<input type="checkbox"/> 15 VIRUS	<input type="checkbox"/> 02 FORMULATION INTERMEDIATE			
<input type="checkbox"/> 69 ANIMALS (Other)	16 OTHER (Specify)	<input type="checkbox"/> 03 DUST			
<input type="checkbox"/> 71 OUTDOOR (Nocrop Agricultural)		<input type="checkbox"/> 04 GRANULAR			
<input type="checkbox"/> 72 OUTDOOR (Resident/Commercial)		<input type="checkbox"/> 05 PELLETTED/TABLETTED			
<input type="checkbox"/> 73 OUTDOOR (Non agricultural)		<input type="checkbox"/> 06 WETTABLE POWDER			
<input type="checkbox"/> 81 BUILDINGS (Agricultural)	6. MODE OF ACTION (Check all that apply)	<input type="checkbox"/> 07 WETTABLE POWDER/DUST			
<input type="checkbox"/> 82 BUILDINGS (Commercial)		<input type="checkbox"/> 08 CRYSTALLINE			
<input type="checkbox"/> 83 BUILDINGS (Food Processing)	<input type="checkbox"/> 01 ATTRACTANT	<input type="checkbox"/> 09 MICROENCAPSULATED			
<input type="checkbox"/> 84 BUILDINGS (Medical)	<input type="checkbox"/> 02 BIOLOGICAL CONTROL	<input type="checkbox"/> 10 IMPREGNATED MATERIALS			
<input type="checkbox"/> 85 BUILDINGS (Residential)	<input type="checkbox"/> 03 CHEMOSTERILANT	<input type="checkbox"/> 11 SELF-GENERATING SMOKE			
<input type="checkbox"/> 91 EQUIPMENT (Commercial)	<input type="checkbox"/> 04 DEFOLIANT	<input type="checkbox"/> 12 EMULSIFIABLE CONCENTRATE			
<input type="checkbox"/> 92 EQUIPMENT (Food)	<input type="checkbox"/> 05 DESICCANT	<input type="checkbox"/> 13 INVERT EMULSION			
<input type="checkbox"/> 93 EQUIPMENT (Agricultural)	<input type="checkbox"/> 06 FEEDING DEPRESSANT	<input type="checkbox"/> 14 FLOWABLE CONCENTRATE			
<input type="checkbox"/> 94 EQUIPMENT (Medical)	<input type="checkbox"/> 07 GROWTH INHIBITOR	<input type="checkbox"/> 15 SOLUBLE CONCENTRATE			
<input type="checkbox"/> 95 EQUIPMENT (Transportation)	<input type="checkbox"/> 08 GROWTH REGULATOR	<input checked="" type="checkbox"/> 16 SOLUTION (Ready to Use)			
<input type="checkbox"/> 96 LAUNDRY AND DRY CLEANING	<input type="checkbox"/> 09 POISON (Single dose)	<input type="checkbox"/> 17 OILS (No added pesticide)			
<input type="checkbox"/> 97 INDUSTRIAL PRESERVATIVES	<input type="checkbox"/> 10 POISON (Multiple Dose)	<input type="checkbox"/> 18 PRESSURIZED (Gas)			
<input type="checkbox"/> 98 PESTICIDE (Manufacturing only)	<input type="checkbox"/> 11 PRESERVATIVE	<input type="checkbox"/> 19 PRESSURIZED (Liquid)			
<input type="checkbox"/> 99 OTHER (Specify)	<input checked="" type="checkbox"/> 12 REPELLENT	<input type="checkbox"/> 20 PRESSURIZED (Dust)			
Humans	<input type="checkbox"/> 13 OTHER (Specify)	<input type="checkbox"/> 21 OTHER (Specify)			

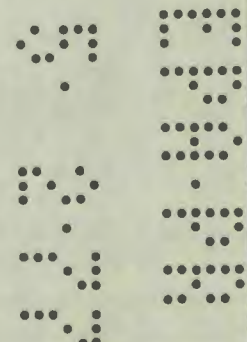
REMARKS

See attached label copy.

BEST DOCUMENT AVAILABLE

Not a NEW submission

Form Approved 151
OMB No. 158-R0066

U.S. ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAM (WH-567) WASHINGTON, D.C. 20460		1. REFERENCE CODE 36864-R		2. EPA USE ONLY - -A1	
APPLICATION FOR NEW PESTICIDE PRODUCT REGISTRATION (Please read instructions on reverse before completing)		3. COMPANY/PRODUCT NO.		4. PROPOSED CLASSIFICATION <input checked="" type="checkbox"/> GENERAL <input type="checkbox"/> RESTRICTED	
5. NAME AND ADDRESS OF APPLICANT (Include ZIP Code) PIERSON LABORATORIES, INC. 2304 W. 105 Leawood, Kansas 66206				6. TYPE OF CONTAINER <input type="checkbox"/> METAL <input checked="" type="checkbox"/> PLASTIC <input type="checkbox"/> GLASS <input type="checkbox"/> PAPER <input type="checkbox"/> OTHER (Specify)	
<input type="checkbox"/> CHECK IF THIS IS A NEW ADDRESS				7. WILL CHILD RESISTANT PACKAGING BE USED? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	
8. PRODUCT NAME CHIGG-AWAY				9. EXPERIMENTAL PERMIT NO. N/A	
10. LOCATION OF LABEL DIRECTIONS <input checked="" type="checkbox"/> ON LABEL <input type="checkbox"/> ON MATERIAL ACCOMPANYING PRODUCT		11. MANNER IN WHICH LABEL IS AFFIXED TO PRODUCT <input checked="" type="checkbox"/> LITHOGRAPH <input type="checkbox"/> OTHER (Specify) <input type="checkbox"/> PAPER GLUED <input type="checkbox"/> STENCILED			
12. TYPES OF DATA SUBMITTED				FOR EPA USE ONLY	
<input type="checkbox"/> 01. NONE				1201	
<input type="checkbox"/> 02. PRODUCT CHEMISTRY				1202	
<input type="checkbox"/> 03. RESIDUE CHEMISTRY				1203	
<input type="checkbox"/> 04. ENVIRONMENTAL CHEMISTRY				1204	
<input checked="" type="checkbox"/> 05. EFFICACY				1205	
<input type="checkbox"/> 06. PHYTOTOXICITY				1206	
<input checked="" type="checkbox"/> 07. HUMAN SAFETY				1207	
<input type="checkbox"/> 08. DOMESTIC ANIMAL SAFETY				1208	
<input type="checkbox"/> 09. FISH AND WILDLIFE SAFETY				1209	
<input type="checkbox"/> 10. BENEFICIAL INSECT SAFETY				1210	
<input type="checkbox"/> 11. ACCIDENT EXPOSURE EXPERIENCE				1211	
<input type="checkbox"/> 12. OTHER (Specify)				1212	
<input type="checkbox"/> 13. OTHER (Specify)				1213	
13. METHOD OF SUPPORT (See instructions) <input checked="" type="checkbox"/> Required Supporting Data Attached. (2A) <input checked="" type="checkbox"/> Required Supporting Data is Submitted by Reference. (2B) <input type="checkbox"/> Proceed on the Basis of Established Use Patterns. (2C)		14. CONTACT POINT Complete items directly below for identification of individual to be contacted, if necessary, to process this application.		15. DATE APPLICATION RECEIVED (Stamped)	
OFFER TO PAY STATEMENT I hereby offer to pay reasonable compensation to the extent provided under Section 3 (c)(1)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, and in accordance with the Regulations and Guidelines published thereunder for use of any test data which has been submitted to the U.S. Environmental Protection Agency in connection with an application for the registration of a pesticide for the first time on or after October 21, 1972 and which may be used in support of the registration application for the subject pesticide.		NAME JAMES D. BENDURE			
		TITLE Vice President			
		TELEPHONE NO. (Include Area Code) 913/642-7871			
16. SIGNATURE James D. Bendure		17. TITLE Vice President			
18. TYPED NAME James D. Bendure		19. DATE SIGNED 3/25/77			

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REPORT OF TELEPHONE CALL OR VISITOR			NOTE: Complete this form. Write "NA" where not applicable.
<input checked="" type="checkbox"/> INCOMING CALL		VISITOR	DATE 10-6-76
OUTGOING CALL		CONGRESSIONAL	TIME OF CALL
NAME AND ADDRESS OF CALLER OR VISITOR 1044 BEHAN			PHONE NO. (Include Area Code or IDS No.)
			REGISTRATION, ID NO. OR FILE SYMBOL
			DATE OF LATEST SUBMISSION
BRIEF SUMMARY OF CONVERSATION inquired about letter submitted at the end of August - Our response was sent 10-1-76.			
ACTION TAKEN OR RECOMMENDED in the course of this conversation Mr. Behan indicated that a lab in Florida (he did not name it) said they would <u>dey lab</u> the tox requirements for section 3 regulations.			
BEST DOCUMENT AVAILABLE			
RECORDED BY (Name) Tim Lander		REFERRED TO (Name)	

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57106

Tom Belan

11304 DUNBROOK RD

Richmond Va

23235

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OCT 1 1976

PIERSON LABORATORIES, INC.
C/O JOHN PIERSON, Jr.
7241 EBY DRIVE
MERIAM, KS. 66204

Subject: CHIGG-AWAY
EPA FILE SYMBOL 36864-R
Application of July 14, 1976

Dear Mr. Pierson:

We have discussed the proposed product with our chemists, toxicologists, and entomologists about this data requirements to support this application for registration. The specific types of tests and information that they require, and as required by law, have been checked off on the enclosure.

This list updates our previous list accompanying our letter of December 23, 1975. While they feel confident that favorable results of the tests will satisfy requirements for registration it is important that you understand that certain results may suggest further testing. This is an inherent characteristic of all scientific studies.

Test methods in the Guidelines for Registering Pesticides (Federal Register June 25, 1975) should be followed for this product's required tests. Please note that there are additional toxicology data requirements since the previous data checklist, but that certain chemistry tests have been deemed unnecessary. Chemistry items 2-16, -22, and -23 are not required for benzocaine, items 2-1, -4, -8 thru -19, -21, and -22 are not required for sulfur, and item 2-28 and -38 are not required for formulated product.

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The information on chigger control Mr. Tom Behan brought to us in January 1975 is only supplementary data to actual test data as we informed him. Actual test data using the product must be submitted to satisfy the efficacy data requirements.

Sincerely,

Timothy A. Gardner
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (WH-567)

WH-567:IRB:TAG:cq:rm.219:WSME:

9/28/76

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GENERAL CHEMISTRY
REQUIREMENTS CHECKLIST

REGISTRATION NO. 36864-R
DATE SUBMITTED

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2-01	Basic Manufacturing Process (for each active ingredient) [162.78(a)] <i>Benzocaine only</i>	S R W N/A O	2-10	Boiling Point (for each active ingredient) [162.78(b)(4)(vi)] <i>Benzo. only</i>	S R W N/A O	2-19	Odor (for each active ingredient) [162.78(b)(4)(xv)] <i>Benzo. only</i>	S R W N/A O
2-02	Purity of Starting and Intermediate Materials Used in Manufacturing Process (for each active ingredient) [162.78(a)]	S R W N/A O	2-11	Vapor Pressure (for each active ingredient) [162.78(b)(4)(vii)] <i>Benzo. only</i>	S R W N/A O	2-20	Complete Composition Including Impurities (for each active ingredient) [162.78(b)(4)(xvi)]	S R W N/A O
2-03	Source of Chemical (for each active ingredient) [162.78(a)]	S R W N/A O	2-12	Density/Specific Gravity (for each active ingredient) [162.78(b)(4)(viii)] <i>Benzo. only</i>	S R W N/A O	2-21	Analytical Methods for Principle Component(s) and Impurities in Technical Chemical for each active ingredient [162.78(c)(2)] <i>Benzo. only</i>	S R W N/A O
2-04	Quality Control Procedures Description (for each active ingredient) [162.78(a)] <i>Benzo. only</i>	S R W N/A O	2-13	Hydrolysis Rate (for each active ingredient) [162.78(b)(4)(ix)] <i>Benzo. only</i>	S R W N/A O	2-22	2-Gram Sample Purified Analytical Standard (for each active ingredient) [162.78(c)(2)]	S R W N/A O
2-05	Common Name (for each active ingredient) [162.78(b)(4)(i)]	S R W N/A O	2-14	Solubility in Various Solvents (for each active ingredient) [162.78(b)(4)(x)] <i>Benzo. only</i>	S R W N/A O	2-23	10 to 20-Gram Sample Batch Chemical (for each active ingredient) [162.78(c)(2)] <i>Sulfur only</i>	S R W N/A O
2-06	Chemical Abstracts Name (for each active ingredient) [162.78(b)(4)(ii)]	S R W N/A O	2-15	Dissociation Constants (for each active ingredient) [162.78(b)(4)(xi)] <i>Benzo. only</i>	S R W N/A O	2-24	Complete Chemical Composition - Confidential Statement of Formula (formulated product) [162.78(b)]	S R W N/A O
2-07	Trade Name (for each active ingredient) [162.78(b)(4)(iii)]	S R W N/A O	2-16	Stability (for each active ingredient) [162.78(b)(4)(xii)]	S R W N/A O	2-25	Basic Manufacturing Process (formulated product) [162.8(b)(3)(1)(B)(2)]	S R W N/A O
2-08	Structural Formula (for each active ingredient) [162.78(b)(4)(iv)] <i>Benzo. only</i>	S R W N/A O	2-17	Physical State (for each active ingredient) [162.78(b)(4)(xiii)] <i>Benzo. only</i>	S R W N/A O	2-26	Analytical Methods for Active Ingredients in Formulation [162.8(b)(3)(1)(B)(4)]	S R W N/A O
2-09	Boiling Point (for each active ingredient) [162.78(b)(4)(v)] <i>Benzo. only</i>	S R W N/A O	2-18	Color (for each active ingredient) [162.78(b)(4)(xiv)] <i>Benzo. only</i>	S R W N/A O	2-27	Miscibility in Various Solvents (formulated product) [162.78(d)(1)]	S R W N/A O

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GENERAL CHEMISTRY
REQUIREMENTS CHECKLIST

REGISTRATION NO. _____
DATE SUBMITTED _____

2-29	pH (formulated product) [162.78(d)(2)]	S R W V/A O	2-37	Weight Active Ingredient(s) per gallon (formulated product) [162.78(d)(6)]	S R W V/A O		
2-29	Boiling Point (formulated product) [162.78(d)(2)]	S R W V/A O	2-38	Storage Stability (formulated product) [162.78(e)]	S R W V/A O		
2-30	Flashpoint (formulated product) [162.78(d)(2)]	S R W V/A O	2-39	Total Tobacco/Smoke Residue Profile (for each active ingredient) [162.78(f)(1)]	S R W V/A O		
2-31	Specific Gravity (formulated product) [162.78(d)(2)]	S R W V/A O	2-40	Follow-up Crop Tobacco Study [162.78(f)(2)]	S R W V/A O		
2-32	Viscosity (formulated Product) [162.78(d)(2)]	S R W V/A O					
2-33	Vapor Pressure (formulated Product) [162.78(d)(2)]	S R W V/A O					
2-34	Explosive Characteristics (formulated product) [162.78(d)(3)]	S R W V/A O					
2-35	Corrosion Hazards (formulated product) [162.78(d)(4)]	S R W V/A O					
2-36	Oxidizing/reducing agent capability (formulated product) [162.78(d)(5)]	S R W V/A O					

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EFFICACY DATA
REQUIREMENTS CHECKLIST

REGISTRATION NO. _____
DATE SUBMITTED _____

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5-1	Site <i>humans</i> Pest <i>chiggers</i> <i>formulated product</i>	S R V N A O	5-10	Site Pest	S R V N A O	
5-2	Site Pest	S R V N A O	5-11	Site Pest	S R V N A O	
5-3	Site Pest	S R V N A O	5-12	Site Pest	S R V N A O	
5-4	Site Pest	S R V N A O	5-13	Site Pest	S R V N A O	
5-5	Site Pest	S R V N A O	5-14	Site Pest	S R V N A O	
5-6	Site Pest	S R V N A O	5-14	Site Pest	S R V N A O	
5-7	Site Pest	S R V N A O	5-14	Site Pest	S R V N A O	
5-8	Site Pest	S R V N A O	5-15	Site Pest	S R V N A O	
5-9	Site Pest	S R V N A O	5-16	Site Pest	S R V N A O	

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PHYTOTOXICITY
(NON-TARGET ORGANISMS)

REGISTRATION NUMBER _____
DATE SUBMITTED _____

6-1	Phytotoxicity (Non-Target organisms) 162.8 (b)(4)(11)(c)	S R W NA O				
6-2	Phytotoxicity (Non-target organisms) 162.8 (b)(4)(11)(c)	S R W NA O				
6-3	Phytotoxicity (Non-target organisms) 162.8 (b)(4)(11)(c)	S R W NA O				
6-4	Phytotoxicity (Non-target organisms) 162.8 (b)(4)(11)(c)	S R W NA O				
6-5	Phytotoxicity (Non-target organisms) 162.8 (b)(4)(11)(c)	S R W NA O				
6-6	Phytotoxicity (Non-target organisms) 162.8 (b)(4)(11)(c)	S R W NA O				
6-7	Phytotoxicity (Non-target organisms) 162.8 (b)(4)(11)(c)	S R W NA O				
6-8	Phytotoxicity (Non-target organisms) 162.8 (b)(4)(11)(c)	S R W NA O				
6-9	Phytotoxicity (Non-target organisms) 162.8 (b)(4)(11)(c)	S R W NA O				

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65.
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TOXICOLOGY DATA
ROUTING SLIP

REGISTRATION NO. 163
DATE SUBMITTED

7-01	Acute Oral LD ₅₀ (rat - for each active ingredient) [162.81(b)(3)(1)]	S R W NA O	7-10	Acute Inhalation LC ₅₀ (rat - for each active ingredient) [162.81(b)(4)(1)(A)]	S R W NA O	7-19	Dermal Sensitization (guinea pig - formulated product) [162.81(b)(4)(11)(A)]	S R W NA O
7-2	Acute Oral LD ₅₀ (rat - formulated product) [162.81(b)(3)(1)]	S R W NA O	7-11	Acute Inhalation LC ₅₀ (rat - formulated product) [162.81(b)(4)(1)(A)]	S R W NA O	7-20	Dermal Photosensitization (guinea pig - for each active ingredient) [162.81(b)(4)(11)(A)]	S R W NA O
7-3	Acute Oral LD ₅₀ (rabbit - for each domestic use dilution) [162.81(b)(3)(1)]	S R W NA O	7-12	Acute Intraperitoneal (rat - for each active ingredient) [162.81(b)(4)(1)(B)]	S R W NA O	7-21	Dermal Photosensitization (guinea pig - formulated product) [162.81(b)(4)(11)(A)]	S R W NA O
7-4	Acute Dermal LD ₅₀ (rabbit - for each active ingredient) [162.81(b)(3)(11)]	S R W NA O	7-13	Acute Intraperitoneal (rat - formulated product) [162.81(b)(4)(1)(B)]	S R W NA O	7-22	Subacute inhalation (rat - formulated product) [162.81(b)(4)(11)(B)]	S R W NA O
7-5	Acute Dermal LD ₅₀ (rabbit - formulated product) [162.81(b)(3)(11)]	S R W NA O	7-14	Acute Intravenous (rat - for each active ingredient) [162.81(b)(4)(1)(B)]	S R W NA O	7-23	Subacute Oral (Non-rodent mammal other than rabbit - for each active ingredient) [162.81(b)(4)(11)(C)]	S R W NA O
7-6	Acute Primary Dermal Irritation (rabbit - for each active ingredient) [162.81(b)(3)(11)]	S R W NA O	7-15	Acute Intravenous (rat - formulated product) [162.81(b)(4)(1)(B)]	S R W NA O	7-24	Subacute Oral (Mammal other than rabbit - for each active ingredient) [162.81(b)(4)(11)(C)]	S R W NA O
7-7	Acute Primary Dermal Irritation (rabbit - formulated product) [162.81(b)(3)(11)]	S R W NA O	7-16	Subacute Dermal (rabbit - for each active ingredient) [162.81(b)(4)(11)(A)]	S R W NA O	7-25	Teratology (mammal with hemochorial placenta - for each active ingredient) [162.81(b)(4)(11)(D)]	S R W NA O
7-8	Acute Primary Eye Irritation (rabbit - for each active ingredient) [162.81(b)(3)(1v)]	S R W NA O	7-17	Subacute Dermal (rabbit - formulated product) [162.81(b)(4)(11)(A)]	S R W NA O	7-26	Neurotoxicity (adult hen - for each active ingredient) [162.81(b)(4)(11)(F)]	S R W NA O
7-9	Acute Primary Eye Irritation (rabbit - formulated product) [162.81(b)(3)(1v)]	S R W NA O	7-18	Dermal Sensitization (guinea pig - for each active ingredient) [162.81(b)(4)(11)(A)]	S R W NA O	7-27	Neurotoxicity (rat or dog - for each active ingredient) [162.81(b)(4)(11)(F)]	S R W NA O

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REGISTRATION NO. _____
DATE SUBMITTED _____

7-28	Metabolism (rat or dog - for each active ingredient) [162.81(b)(4)(ii)(F)]	S	7-36	Mutagenicity - in vivo cytogenetic test (rat or mouse - for each active ingredient) [162.81(b)(4)(iv)(A)]	S	✓	Human patch tests
		R			R		
		W			W		
		NA			NA		
7-29	Metabolism (other species depending on use pattern - for each active ingredient) [162.81(b)(4)(ii)(F)]	O	7-37	Mutagenicity - specific locus test (mouse - for each active ingredient) [162.81(b)(4)(iv)(A)]	O		
		S			S		
		R			R		
		W			W		
7-30	Oncogenicity (rat - for each active ingredient) [162.81(b)(4)(iii)(A)]	NA	7-38	Potentiation (for each active ingredient) [162.81(b)(4)(iv)(B)]	NA		
		O			O		
		S			S		
		R			R		
7-31	Oncogenicity (most-sensitive mammalian species other than rat - for each active ingredient) [162.81(b)(4)(iii)(A)]	W	7-39	Re-entry (formulated product) [162.81(b)(4)(iv)(C)]	W		
		NA			NA		
		O			O		
		S			S		
7-32	Chronic feeding (rat - for each active ingredient) [162.81(b)(4)(iii)(B)]	R	7-40	Diagnostic Information [162.81(b)(4)(i)(c)]	R		
		W			W		
		NA			NA		
		O			O		
7-33	Chronic Feeding (other species as determined by Reg.Div. - for each active ingredient) [162.81(b)(4)(iii)(B)]	S	7-41	First-aid information [162.81(b)(4)(i)(c)]	S		
		R			R		
		W			W		
		NA			NA		
7-34	Reproduction (same rodent as chronic feeding study - for each active ingredient) [162.81(b)(4)(iii)(C)]	O	7-42	Palliative Information [162.81(b)(4)(i)(c)]	O		
		S			S		
		R			R		
		W			W		
7-35	Mutagenicity - heritable translocation test (mouse - for each active ingredient) [162.81(b)(4)(iv)(A)]	NA	7-43	Antidotal Information [162.81(b)(4)(i)(c)]	NA		
		O			O		
		S			S		
		R			R		

* may be required in future as guidelines will be published in the Federal Register.

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FISH AND WILDLIFE DATA
REQUIREMENTS CHECKLIST

REGISTRATION NO. _____
DATA SUBMITTED

9-01	Avian Acute Oral LD ₅₀ Mallard or Bobwhite each active ingredient 162.82(a) 162.82(c)(1)(i)	S R W O	9-10	Acute Toxicity, 96-hour LC ₅₀ (shrimp-for each active ingredient) 162.82(c) 162.82(2)(1)(v)	S R W O	9-19	Invertebrate Reproduction Study (for each active ingredient) 162.82(c) 162.82(2)(1)(B)	S R W N/A O
9-02	Avian Subacute Dietary LC ₅₀ (Mallard-for each active ingredient) 162.82(a) 162.82(c)(1)(ii)	S R W O	9-11	Acute Toxicity, 96-hour LC ₅₀ (shrimp-formulated product) 162.82(c) 162.82(2)(1)(B)	S R W O	9-20	Invertebrate Reproduction Study (formulated product) 162.82(c) 162.82(B)	S R W N/A O
9-03	Avian Subacute Dietary LC ₅₀ (Bobwhite quail-for each active ingredient) 162.82(a) (c)(1)(ii)	S R W O	9-12	Acute Toxicity, 96-hour LC ₅₀ (crabs-for each active ingredient) 162.82(c) 162.82(2)(1)(B)	S R W O	9-21	Field Study (formulated product) 162.82(c) 162.82(2)(1)(A)	S R W N/A O
9-04	Fish Acute Toxicity, 96-hour LC ₅₀ (rainbow trout-for each active ingredient) 162.82(a) 162.82(c)(1)(iii)	S R W O	9-13	Acute Toxicity, 96-hour LC ₅₀ (crabs-formulated product) 162.82(c) 162.82(2)(1)(B)	S R W O	9-22	Simulated Field Study (formulated product) 162.82(c) 162.82(2)(1)(A)	S R W N/A O
9-05	Fish Acute Toxicity 96-hour LC ₅₀ (rainbow trout- formulated product) 162.82(c) 162.82(1)(iii)	S R W O	9-14	96-hour Acute Oyster Larvae LC ₅₀ --or-- American Oyster Shell Deposition (for each active ingredient) 162.82(c)(2)(1)(C)	S R W O			
9-06	Fish Acute Toxicity 96-hour LC ₅₀ (bluegill-for each active ingredient) 162.82(a) 162.82(c)(1)(iii)	S R W O	9-15	96-hour Acute Oyster Larvae LC ₅₀ --or-- American Oyster Shell Deposition (formulated product) 162.82(c)(2)(1)(C)	S R W O			
9-07	Fish Acute Toxicity 96-hour LC ₅₀ (bluegill-formulated product) 162.82(c)(1)(iii)	S R W O	9-16	Reproduction (Avian) (Bobwhite-for each active ingredient) 162.82(c) 162.82(2)(1)(A)	S R W O			
9-08	Invertebrate Acute Toxicity, 96-hour LC ₅₀ (Daphnia-for each active ingredient) 162.82(a) 162.82(c)(1)(iv)	S R W O	9-17	Reproduction (Avian) (Mallard-for each active ingredient) 162.82(c) 162.82(2)(1)(A)	S R W O			
9-09	Invertebrate Acute Toxicity, 96-hour LC ₅₀ (Daphnia-formulated product) 162.82(a) 162.82(c)(1)(iv)	S R W O	9-18	Chronic or Partial Chronic Fish Study (fathead minnow-for each active ingredient) 162.82(c)(2)(1)(A)	S R W O			

Tox

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add to 12-23-75 tox reg

→ 7-7

→ 7-20

→ 7-25

note type - this should be familiar

→ initial FR for publication of
~~the~~ new guidelines which
may require → 7-35

~~the list would now look like this~~

7 - 1

17

2

18

4

19

5

20

6

25

7

patent tests

8

9

and maybe 35

16

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Chem —

Sulfur

2-1 not needed for sulfur

4

8

13

18

9

14

19

10

15

21

11

16

22

12

17

22
stop

Benzocaine

2-16

22

23

not need for Benzocaine

formulation

2-28

38

not needed

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→ make statement about running tests in accordance with guidelines

→ Tox - adds

→ Chem - many deletions for sulfur because a decision has been reached that this info is not needed on inorganic chemicals

also note that items 2-16, 22 and 23 are not needed for Benzocaine

items 2-28 and 38 are not needed on the formulation

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PIERSON ENTERPRISES

169
JOHN T. PIERSON, JR.
PRESIDENT

7241 EBY DRIVE
SHAWNEE MISSION, KANSAS 66204
PHONE: (913) 362-4364

July 14, 1976

Via Hand Delivery - Tom Behan

Mr. Tim Gardner
Environmental Protection Agency
Washington, D.C.

36864-R

Dear Mr. Gardner:

I am writing this letter in behalf of Pierson Laboratories in order to confirm with you our understanding of what the EPA is requiring our company to do before your agency will assign a number to our product, Chigg-Away.

At various times you have talked with Mr. Tom Behan, Mr. Jim Bendure and Dr. John Doull, Head of Department of Pharmacology and Toxicology at the Kansas University Medical Center, and in view of the number of people contacted I felt it important to clarify what we understand your requirements to be.

It is also important to your understanding to know that Pierson Laboratories is a relatively new partnership with - at this point - limited financial means and we cannot afford to have only a partial understanding of what the EPA requires. I have felt in our previous relationship that on occasion we would comply with one request only to find that additional data was then being asked. If we proceed with the testing you are now requiring at considerable expense we will not be able to incur further testing as that could very well have the effect of putting us out of business. I know you would like to avoid this as much as would we.

By way of background, Dr. Doull phoned you on May 21 and passed along his evaluation that "Chigg-Away" is the type of product which, in his professional opinion, should require no additional testing as so much is already available on the basic ingredients being used. Dr. Doull has informed us that you rejected that evaluation and that the EPA could issue us a number only if we submitted test results for:

88
BEST DOCUMENT AVAILABLE

296
3-24-76
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HJ

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Mr. Tim Gardner
Page Two

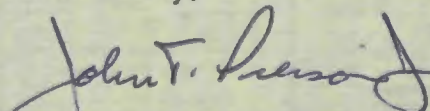
1. Acute Oral Toxicity
2. Dermal Toxicity
3. Eye Irritation

Additionally, Mr. Behan has given you personally a copy of test results done by Dr. Joseph Borzelleca, Head of the Department of Pharmacology, Virginia Medical College, indicating a complete lack of dermal toxicity and eye irritation for "Chigg-Away".

It is our understanding that you have rejected the evaluations described above of both Dr. Doull and Dr. Borzelleca.

I would appreciate your written confirmation by return mail that the EPA will give a number to our product, Chigg-Away, after we run the three tests indicated above and the results meet with your satisfaction.

Sincerely,



John T. Pierson, Jr.
President
PIERSON LABORATORIES

JTP, Jr.:gs

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Rec'd 8-24-76
56
H3

SUBMISSION REVIEW RECORD				1. REGISTRATION NUMBER				CYCLE	2. DATE RECEIVED		
3. 3CID PUBLICATION NECESSARY				4. PETITION NO.				5. RECEIVED PM TEAM			
6. METHOD OF SUPPORT				7. PRODUCT MANAGER				NO.	8. PROJECTED RETURN		
9. DATE PULLED				10. DATE PUBLISHED				11. ACTION TYPE			
12. OUTGOING DATE				DATE REVIEW COMPLETED				COM-MENT CODE			
REV. SEC.	REVIEW TYPE CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER				COM-MENT CODE	MO	DAY	YR
	A	REVIEWABILITY TEAM									
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW	JBR	T.A. GARDNER				15			
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW									
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW									
	E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW									
	F	PRODUCT MANAGER									
	G	INTERAGENCY REFERRAL									
	H	COST-BENEFIT REVIEW									
	I	PUBLIC COMMENTS REVIEW									
	J	EEE BRANCH INSECTICIDE EFFICACY									
	K	EEE BRANCH HERBICIDE EFFICACY									
	L	EEE BRANCH FUNGICIDE EFFICACY									
	M	EEE BRANCH RODENTICIDE EFFICACY									
	N	EEE BRANCH DISINFECTANT EFFICACY									
	O	CHEMISTRY BRANCH RESIDUE CHEMISTRY									
	P	EEE BRANCH ENVIRONMENTAL CHEMISTRY									
	Q	TOXICOLOGY BRANCH HUMAN SAFETY									
	R	EEE BRANCH ENVIRONMENTAL SAFETY									
	S										
	T										
PRODUCT MANAGER SIGNATURE				TYPE OF RESPONSE				CODE			
				OCT 1 1976							

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REPORT OF TELEPHONE CALL OR VISITOR			NOTE: Complete this form. Write "NA" where not applicable.
INCOMING CALL	X	VISITOR	DATE 1-16-75
OUTGOING CALL		CONGRESSIONAL	TIME OF CALL visit
NAME AND ADDRESS OF CALLER OR VISITOR Mr. Behan Pierson Labs Mesa, AZ			PHONE NO. (Include Area Code or IDS No.) 804-794-8507
			REGISTRATION, ID NO. OR FILE SYMBOL 36864-R Chig's Away
			DATE OF LATEST SUBMISSION
BRIEF SUMMARY OF CONVERSATION Came in to ask some questions, discuss problems with Chig's Away. Behan brought two reports concerning sulfur, its chem, biol. properties.			
ACTION TAKEN OR RECOMMENDED Told him the reports only supplementary data - explained to him what else is needed. I went through our 12/23/75 ltr. & Data Requirements check-list with him. Emphasized & explained why all these data requirements are necessary & that FDA/BD's review was not meant to be taken as FDA <u>accepts</u> product but that "FDA does not accept, & does not object" - interim review. Behan said later in afternoon telephoned that co. has gotten eff. date together, that co. has hired a consultant (Lou Mitchell) to handle their registration.			
BEST DOCUMENT AVAILABLE			
RECORDED BY (Name) J. Ellenberger w/ Harvey Warnick		REFERRED TO (Name) 2	

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REPORT OF TELEPHONE CALL OR VISITOR			NOTE: Complete this form. Write "NA" where not applicable.
<input type="checkbox"/>	INCOMING CALL	<input type="checkbox"/>	DATE 1-16-75
<input checked="" type="checkbox"/>	OUTGOING CALL	<input type="checkbox"/>	TIME OF CALL 12:00 noon
NAME AND ADDRESS OF CALLER OR VISITOR Robert Heller FDA/BD Rockville, MD			PHONE NO. (Include Area Code or IDS No.) 443-3750
			REGISTRATION, ID NO. OR FILE SYMBOL 36864-R Chugg-Away
			DATE OF LATEST SUBMISSION

BRIEF SUMMARY OF CONVERSATION

Told Heller I wanted to ask about his ~~the~~ ~~the~~ comments in our 12/23/75 ltr. to company and how this relates to FDA/BD interim review of such products.

ACTION TAKEN OR RECOMMENDED

Heller explained what the interim review really means. BD is not looking for toxicological possibilities in a product as they are temporarily deferring it to the OTC Drug Review. FDA has not received enough information at this time to make final conclusions about this ~~the~~ product's formula, claims or other miscellaneous preparations. So, as an interim measure, until a determination is made, FDA/BD permits company to market product (w/ EPA's concurrence) ~~with if~~ but ~~tell~~ telling them that when a determination is made company is subject to any new restrictions FDA will have. In essence, "FDA has NOT approved Chugg-Away" but it has not objected either." FDA sees no imminent hazard at this time.

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MICROFICHE CREATED

DATE: MAY 18 1981 MAY 18 1981

RECORDED BY (Name)

REFERRE

J. Ellinger

1 of 211

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JAN 7 1976

Mr. Tom Behan, Chigg-Away, File Symbol 36864-R
Pierson Laboratories, Meriam, Kansas

Director
Registration Division (MH-567)

Deputy Associate Administrator for Pesticides (MH-566)

Mr. Behan's company has had four address changes and several company name changes since the initial filing of his application without notifying the Division of any changes. Consequently correspondence sent to his original address apparently was not forwarded to him at his new addresses by the Postal Service nor was any of it returned to the Division. During the ongoing loss of contact the Section 3 Regulations became effective placing him under the stricter procedures.

The mailing address was not Mr. Behan's only problem because after the initial filing he has changed his formula, his use patterns, and label claims. Mr. Behan's product is now a combination pesticide-"old" drug which still requires joint approval by the Bureau of Veterinary Medicine, FDA and EPA prior to acceptance by either.

We have been in contact with Mr. Behan and Mr. Pierson on December 23, 1975, and explained by telephone the situation and how to resolve it. We have also written them reaffirming our telephone conversation. There is no simple way to resolve this company's problems. The company officials are not pleased with the situation, but do understand the reasons for their problem now.

John B. Ritten, Jr.

MH-567:IRB:RTroast:HSHarrison:gaf: rm 243 MSME, X69425: 1/7/76

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*memo from Mr. Ritten to
DAA Ed Johnson in response
to Regional Administrators inquiry*

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REPORT OF TELEPHONE CALL OR VISITOR			NOTE: Complete this form. Write "NA" where not applicable.
<input checked="" type="checkbox"/> INCOMING CALL		VISITOR	DATE 12-23-75
<input type="checkbox"/> OUTGOING CALL		CONGRESSIONAL	TIME OF CALL 1:30
NAME AND ADDRESS OF CALLER OR VISITOR John Pearson			PHONE NO. (Include Area Code or IDS No.)
			REGISTRATION, ID NO. OR FILE SYMBOL 36864-12
			DATE OF LATEST SUBMISSION
BRIEF SUMMARY OF CONVERSATION wanted copy of our 6-4-75 letter also wanted to change address again			
ACTION TAKEN OR RECOMMENDED Pearson Salvatore's John Pearson Jr 7241 EBT Drive Merion Kansas 66204 BEST DOCUMENT AVAILABLE copy sent today 12-23-75 also, talked about this situation with Mr Pearson, Mr Behan, and Joe Pochin (EPA Region)			
RECORDED BY (Name) Tom Gaudin		REFERRED TO (Name) 20	

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23 SEP 1975

Pierson Laboratories, Inc.
c/o Patterson Chemical Co.
1400 Union Avenue
Kansas City, MO 64101

Gentlemen:

Subject: Chigg-Away
File Symbol 36864-R

The proposed label and formulation submitted for Chigg-Away indicate it is a product containing precipitated sulfur and benzocaine for the relief of itching and discomfort of bites from various non-poisonous insects. The product is, therefore, a drug for human use subject to the requirements of the Food, Drug, and Cosmetic Act (FDAC Act). In addition the label claims the product will repel chiggers causing it to be subject also to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

The following comments have been made by FDA/Bureau of Drugs:

The Over-the-Counter Drug Review (OTC Drug Review) of the FDA currently in progress is expected to review such preparations as this in its review of miscellaneous topical OTC drug preparations. A call for data has already been published in the Federal Register and a panel has convened to review such products for safety and efficacy.

Until the panel has concluded their recommendations and a finalized monograph covering such OTC products as this has been published in the Federal Register, we request certain interim label changes in the interest of safety in order for the product to be deferred to the OTC Drug Review. In addition, should EPA approve registration based on the claims applicable to FIFRA, Pierson Laboratories, Inc. must be informed that the marketing of "CHIGG-AWAY" at this time must be solely under their own responsibility with the realization that the results of the OTC Drug Review may affect the continued marketing of the drug.

The interim label changes are as follows and should be included on all labeling as well:

1. The phrase "Do Not Take Internally" should be inserted after a hyphen following "For External Use Only".

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Page 2

2. The sentence beginning with "Discontinue use..." in the back panel "Caution" should be removed and replaced with the following "Not for prolonged use". If the condition for which this preparation is used persists or if a rash or irritation develops, discontinue use and consult physician".

3. The panel reviewing OTC topical analgesic preparations has expressed their concern over the use of benzocaine in infants due to the risk of possible methemoglobinemia. Although their conclusions are tentative and not final, we believe the warning suggested by the panel against use of benzocaine in infants should be included on any new benzocaine containing product proposing to enter the market. Therefore, the following statement should be placed separately and directly below the "Caution" statement on the back panel: "Caution: Not to be used in infants younger than two years because of risk of methemoglobinemia".

We are infamiliar with the use of benzocaine at this extremely low level of 0.05% for topical anesthetic purposes, and we question the efficacy of its use at that level for that purpose.

The following comments pertain to requirements of EPA:

As mentioned above this product must be included as a pesticide because of the claim "repels"; without this claim the product would not be subject to the requirements issued by EPA, only to those of FDA. Enclosed are the data requirements--chemistry, efficacy, and toxicology--noted on the checklist. Each specific piece of information must be submitted or specifically referenced where it may be found. When these data requirements are completed a label review will commence.

Also enclosed in case you may not have the publications are the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, the Regulations, and Guidelines for registering a pesticide product.

Sincerely,

Timothy A. Gardner
Product Manager (15)
Insecticide-Rodenticide Branch
Registration Division (WH-567)

Enclosure Guidelines

WH-567:IRB:TAGARDNER:bab:rm 219 WSME, x68815:12/22/75

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ENVIRONMENTAL CHEMISTRY DATA
REQUIREMENTS CHECKLIST

REGISTRATION NO. _____
DATE SUBMITTED _____

4-01	Basic Soil Metabolism, Aerobic (for each active ingredient) [162.8(b)(3)(ii); 162.79(a)(2)(v)]	S R W NA O	4-10	Leaching Studies - Field (formulated product) [162.8(b)(3)(ii); 162.79(a)(4)]	S R W NA O	4-19	Moving Water Tests (formulated product) [162.8(b)(3)(ii); 162.79(b)(6)]	S R W NA O
4-02	Abbreviated Soil Metabolism, Aerobic, Fine Textured Soil (for each active ingredient) [162.8(b)(3)(ii); 162.79(a)(2)(vi)]	S R W NA O	4-11	Hydrolysis (for each active ingredient) [162.8(b)(3)(ii); 162.79(b)(1)(i)]	S R W NA O	4-20	Fish Residue Studies (for each active ingredient) [162.8(b)(3)(ii); 162.79(c)(1)(i)]	S R W NA O
4-03	Soil Metabolism, Additional Bound Residue Studies (for each active ingredient) [162.8(b)(3)(ii); 162.79(a)(2)(vii)]	S R W NA O	4-12	Degradation in Water Containing Suspended Solids (for each active ingredient) [162.8(b)(3)(ii); 162.79(b)(2)]	S R W NA O	4-21	Modified Fish Exposure Studies (for each active ingredient) [162.8(b)(3)(ii); 162.79(c)(1)(iii)]	S R W NA O
4-04	Soil Metabolism, Additional Tests - Bound Residues (for each active ingredient) [162.8(b)(3)(ii); 162.79(a)(2)(viii)]	S R W NA O	4-13	Degradation in Bottom Sediments (for each active ingredient) [162.8(b)(3)(ii); 162.79(b)(3)]	S R W NA O	4-22	Fish/Aquatic Organism Simulated Field Studies (for each active ingredient) [162.8(b)(3)]	S R W NA O
4-05	Soil Metabolism, Anaerobic (for each active ingredient) [162.8(b)(3)(ii); 162.79(a)(2)(ix)]	S R W NA O	4-14	Translocation: Uptake from Aquatic Sources by Crops and Aquatic Plants (for each active ingredient) [162.8(b)(3)(ii); 162.79(b)(4)]	S R W NA O	4-23	Terrestrial Wildlife Residue Studies (for each active ingredient) [162.8(b)(3)(ii); 162.79(c)(1)(iv)]	S R W NA O
4-06	Soil Persistence (formulated product) [162.8(b)(3)(ii); 162.79(a)(3)(i)]	S R W NA O	4-15	Translocation: Uptake from Aquatic Sources by Crops and Aquatic Plants (formulated product) [162.8(b)(3)(ii); 162.79(b)(4)(i)]	S R W NA O	4-24	Crop Uptake - Soil (for each active ingredient) [162.79(c)(2)]	S R W NA O
4-07	Soil Persistence, Supplementary Studies - Direct Incorporation (formulated product) [162.8(b)(3)(ii); 162.79(a)(3)(iv)]	S R W NA O	4-16	Translocation: Irrigation Studies (for each active ingredient) [162.79(b)(4)(ii)]	S R W NA O	4-25	Crop Uptake - Soil (formulated product) [162.79(c)(2)]	S R W NA O
4-08	Soil Persistence, Long Term Studies (formulated product) [162.8(b)(3)(ii); 162.79(a)(3)(v)]	S R W NA O	4-17	Translocation: Irrigation Studies (formulated product) [162.79(b)(4)(ii)]	S R W NA O	4-26	Photodegradation - Surface (for each active ingredient) [162.79(d)]	S R W NA O
4-09	Leaching Studies - Laboratory (for each active ingredient) [162.8(b)(3)(ii); 162.79(a)(4)]	S R W NA O	4-18	Livestock and Poultry Drinking Water/Milk, Tissue, Egg Residues (for each active ingredient) [162.8(b)(3)(ii); 162.79(b)(5)]	S R W NA O	4-27	Photodegradation - Aqueous (for each active ingredient) [162.8(b)(3)(ii); 162.79(b)(1)(ii); (d)]	S R W NA O

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ENVIRONMENTAL CHEMISTRY DATA
REQUIREMENTS CHECKLIST

REGISTRATION NO. _____
DATE SUBMITTED _____

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4-28	Photodegradation - Air (for each active ingredient) [162.79(d)]	S R W NA O			
4-29	Volatilization (for each active ingredient) [162.8(b)(3)(11); 162.79(e)] 162.79(f)	S R W NA O			
4-30	Effect on Micro-organisms (for each active ingredient) [162.8(b)(3)(11); 162.79(f)(1)]	S R W NA O			
4-31	Effect of Micro-organisms on Pesticides (for each active ingredient) [162.8(b)(3)(11); 162.79(f)(2)]	S R W NA O			
4-32	Pesticide and Container Disposal Information [162.8(b)(3)(11)(3)]	S R W NA O			

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DATA REQUIREMENTS

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CHIGGS-AWAY

GENERAL CHEMISTRY
REQUIREMENTS CHECKLIST

REGISTRATION NO. 36864-R
DATE SUBMITTED

2-01	Basic Manufacturing Process (for each active ingredient) [162.78(a)]	S R W N/A O	2-10	Boiling Point (for each active ingredient) [162.78(b)(4)(vi)]	S R W N/A O	2-19	Odor (for each active ingredient) [162.78(b)(4)(xv)]	S R W N/A O
2-02	Purity of Starting and Intermediate Materials Used in Manufacturing Process (for each active ingredient) [162.78(a)]	S R W N/A O	2-11	Vapor Pressure (for each active ingredient) [162.78(b)(4)(vii)]	S R W N/A O	2-20	Complete Composition Including Impurities (for each active ingredient) [162.78(b)(4)(xvi)]	S R W N/A O
2-03	Source of Chemical (for each active ingredient) [162.78(a)]	S R W N/A O	2-12	Density/Specific Gravity (for each active ingredient) [162.78(b)(4)(viii)]	S R W N/A O	2-21	Analytical Methods for Principle Component(s) and Impurities in Technical Chemical for each active ingredient [162.78(c)(2)]	S R W N/A O
2-04	Quality Control Procedures Description (for each active ingredient) [162.78(a)]	S R W N/A O	2-13	Hydrolysis Rate (for each active ingredient) [162.78(b)(4)(ix)]	S R W N/A O	2-22	2-Gran Sample Purified Analytical Standard (for each active ingredient) [162.78(c)(2)]	S R W N/A O
2-05	Common Name (for each active ingredient) [162.78(b)(4)(i)]	S R W N/A O	2-14	Solubility in Various Solvents (for each active ingredient) [162.78(b)(4)(x)]	S R W N/A O	2-23	10 to 20-Gran Sample Batch Chemical (for each active ingredient) [162.78(c)(2)]	S R W N/A O
2-06	Chemical Abstracts Name (for each active ingredient) [162.78(b)(4)(ii)]	S R W N/A O	2-15	Dissociation Constants (for each active ingredient) [162.78(b)(4)(xi)]	S R W N/A O	2-24	Complete Chemical Composition - Confidential Statement of Formula (formulated product) [162.78(b)]	S R W N/A O
2-07	Trade Name (for each active ingredient) [162.78(b)(4)(iii)]	S R W N/A O	2-16	Stability (for each active ingredient) [162.78(b)(4)(xii)]	S R W N/A O	2-25	Basic Manufacturing Process (formulated product) [162.78(b)(3)(i)(B)(2)]	S R W N/A O
2-08	Structural Formula (for each active ingredient) [162.78(b)(4)(iv)]	S R W N/A O	2-17	Physical State (for each active ingredient) [162.78(b)(4)(xiii)]	S R W N/A O	2-26	Analytical Methods for Active Ingredients in Formulation [162.78(b)(3)(i)(B)(4)]	S R W N/A O
2-09	Melting Point (for each active ingredient) [162.78(b)(4)(v)]	S R W N/A O	2-18	Color (for each active ingredient) [162.78(b)(4)(xiv)]	S R W N/A O	2-27	Miscibility in Various Solvents (formulated product) [162.78(b)(1)]	S R W N/A O

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178A

MEMORANDUM
OF CALL

TO:

Mr. H. Hanson

☒ YOU WERE CALLED BY—

☐ YOU WERE VISITED BY—

Mr. Joe Postin

OF (Organization)

Pesticide Div. Kansas City

☐ PLEASE CALL —→

PHONE NO.
CODE/EXT. _____

☐ WILL CALL AGAIN

☐ IS WAITING TO SEE YOU

☐ RETURNED YOUR CALL

☐ WISHES AN APPOINTMENT

MESSAGE

Please call Mr. Thomas Behan
Phone - 913-888-9672

Mr. Behan is complaining
about his lost pocket and
would like for you to call him
or write him. If not Mr. Behan
is threaten to go to him Congress.

RECEIVED BY

gpc

DATE

12/10

TIME

3:10

STANDARD FORM 63

REVISED AUGUST 1967

GSA FPMR (41 CFR) 101-11.6

GPO : 1969-048-10-00000-23-880

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63-108

17A

~~178A~~

178B

Person tobs

36 864-R

Chig-A-Way - human repellent
after Sect 3 logs + sent back

~~XXXXX~~

9515 Monrovia
Lemay Ku
66217

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GENERAL CHEMISTRY
COMPLETION CHECKLIST

REGISTRATION NO. _____
DATE SUBMITTED _____

2-28	MI (formulated product)	S R W /A O	2-37	Weight Active Ingre- dient(s) per gallon (formulated product)	S R W /A O		
✓	[162.78(d)(2)]		✓	[162.78(d)(6)]			
2-29	Boiling Point (formulated product)	S R W /A O	2-38	Storage Stability (formulated product)	S R W /A O		
✓	[162.78(d)(2)]		✓	[162.78(e)]			
2-30	Flashpoint (formulated product)	S R W /A O	2-39	Total Tobacco/Smoke Residue Profile (for each active ingredient)	S R W /A O		
✓	[162.78(d)(2)]			[162.78(f)(1)]			
2-31	Specific Gravity (formulated product)	S R W /A O	2-40	Follow-up Crop Tobacco Study	S R W /A O		
✓	[162.78(d)(2)]			[162.78(f)(2)]			
2-32	Viscosity (formulated Product)	S R W /A O					
✓	[162.78(d)(2)]						
2-33	Vapor Pressure (formulated Product)	S R W /A O					
✓	[162.78(d)(2)]						
2-34	Explosive Character- istics (formulated product)	S R W /A O					
✓	[162.78(d)(3)]						
2-35	Corrosion Hazards (formulated product)	S R W /A O					
✓	[162.78(d)(4)]						
2-36	Oxidizing/reducing agent capability (formulated product)	S R W /A O					
✓	[162.78(d)(5)]						

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Data required for each site/pest combination

EFFICACY DATA
REQUIREMENTS CHECKLIST

3-1	Site <i>humans</i> Pest <i>chiggers</i> <i>-repell</i>	S R W NA O	3-10	Site Pest	S R W NA O		
3-2	Site Pest	S R W NA O	3-11	Site Pest	S R W NA O		
3-3	Site Pest	S R W NA O	3-12	Site Pest	S R W NA O		
3-4	Site Pest	S R W NA O	3-13	Site Pest	S R W NA O		
3-5	Site Pest	S R W NA O	3-14	Site Pest	S R W NA O		
3-6	Site Pest	S R W NA O	3-14	Site Pest	S R W NA O		
3-7	Site Pest	S R W NA O	3-14	Site Pest	S R W NA O		
3-8	Site Pest	S R W NA O	3-15	Site Pest	S R W NA O		
3-9	Site Pest	S R W NA O	3-16	Site Pest	S R W NA O		

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None currently required.

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ENVIRONMENTAL CHEMISTRY DATA
SCHEDULE 1 CHECKLIST

REGISTRATION NO.
DATA SUBMITTED

4-01	Basic Soil Metabolism, Aerobic (for each active ingredient) [162.8(b)(3)(ii); 162.79(a)(2)(v)]	S R W NA O	4-10	Leaching Studies - Field (for formulated product) [162.8(b)(3)(ii); 162.79(a)(4)]	S R W NA O	4-19	Moving Water Tests (for formulated product) [162.8(b)(3)(ii); 162.79(b)(6)]	S R W NA O
4-02	Abbreviated Soil Metabolism, Aerobic, Fine Textured Soil (for each active ingredient) [162.8(b)(3)(ii); 162.79(a)(2)(vi)]	S R W NA O	4-11	Hydrolysis (for each active ingredient) [162.8(b)(3)(ii); 162.79(b)(1)(i)]	S R W NA O	4-20	Fish Residue Studies (for each active ingredient) [162.8(b)(3)(ii); 162.79(c)(1)(i)]	S R W NA O
4-03	Soil Metabolism, Additional Bound Residue Studies (for each active ingredient) [162.8(b)(3)(ii); 162.79(a)(2)(vii)]	S R W NA O	4-12	Degradation in Water Containing Suspended Solids (for each active ingredient) [162.8(b)(3)(ii); 162.79(b)(2)]	S R W NA O	4-21	Modified Fish Exposure Studies (for each active ingredient) [162.8(b)(3)(ii); 162.79(c)(1)(ii)]	S R W NA O
4-04	Soil Metabolism, Additional Tests - Bound Residues (for each active ingredient) [162.8(b)(3)(ii); 162.79(a)(2)(viii)]	S R W NA O	4-13	Degradation in Bottom Sediments (for each active ingredient) [162.8(b)(3)(ii); 162.79(b)(3)]	S R W NA O	4-22	Fish/Aquatic Organism Simulated Field Studies (for each active ingredient) [162.8(b)(3)]	S R W NA O
4-05	Soil Metabolism, Anaerobic (for each active ingredient) [162.8(b)(3)(ii); 162.79(a)(2)(ix)]	S R W NA O	4-14	Translocation: Uptake from Aquatic Sources by Crops and Aquatic Plants (for each active ingredient) [162.8(b)(3)(ii); 162.79(b)(4)]	S R W NA O	4-23	Terrestrial Wildlife Residue Studies (for each active ingredient) [162.8(b)(3)(ii); 162.79(c)(1)(iv)]	S R W NA O
4-06	Soil Persistence (formulated product) [162.8(b)(3)(ii); 162.79(a)(3)(i)]	S R W NA O	4-15	Translocation: Uptake from Aquatic Sources by Crops and Aquatic Plants (formulated product) [162.8(b)(3)(ii); 162.79(b)(4)(i)]	S R W NA O	4-24	Crop Uptake - Soil (for each active ingredient) [162.79(c)(2)]	S R W NA O
4-07	Soil Persistence, Supplementary Studies - Direct Incorporation (formulated product) [162.8(b)(3)(ii); 162.79(a)(3)(ii)]	S R W NA O	4-16	Translocation: Irrigation Studies (for each active ingredient) [162.79(b)(4)(ii)]	S R W NA O	4-25	Crop Uptake - Soil (formulated product) [162.79(c)(2)]	S R W NA O
4-08	Soil Persistence, Long Term Studies (formulated product) [162.8(b)(3)(ii); 162.79(a)(3)(v)]	S R W NA O	4-17	Translocation: Irrigation Studies (formulated product) [162.79(b)(4)(ii)]	S R W NA O	4-26	Photodegradation - Surface (for each active ingredient) [162.79(d)]	S R W NA O
4-09	Leaching Studies - Laboratory (for each active ingredient) [162.8(b)(3)(ii); 162.79(a)(4)]	S R W NA O	4-18	Livestock and Poultry Drinking Water/Milk, Tissue, Egg Residues (for each active ingredient) [162.8(b)(3)(ii); 162.79(b)(5)]	S R W NA O	4-27	Photodegradation - Aquatic (for each active ingredient) [162.8(b)(3)(ii); 162.79(b)(1)(ii), (c)]	S R W NA O

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PHYTOTOXICITY
(NON-TARGET ORGANISMS)

6-1	Phytotoxicity (Non-Target organisms) 162.8 (b)(4)(11)(c)	S R W NA O				
6-2	Phytotoxicity (Non-target organisms) 162.8 (b)(4)(11)(c)	S R W NA O				
6-3	Phytotoxicity (Non-target organisms) 162.8 (b)(4)(11)(c)	S R W NA O				
6-4	Phytotoxicity (Non-target organisms) 162.8 (b)(4)(11)(c)	S R W NA O				
6-5	Phytotoxicity (Non-target organisms) 162.8 (b)(4)(11)(c)	S R W NA O				
6-6	Phytotoxicity (Non-target organisms) 162.8 (b)(4)(11)(c)	S R W NA O				
6-7	Phytotoxicity (Non-target organisms) 162.8 (b)(4)(11)(c)	S R W NA O				
6-8	Phytotoxicity (Non-Target organisms) 162.8 (b)(4)(11)(c)	S R W NA O				
6-9	Phytotoxicity (Non-target organisms) 162.8 (b)(4)(11)(c)	S R W NA O				

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TOXICOLOGY DATA
EXPERIMENTAL CHECKLIST

REGISTRATION NO.
DATE SUBMITTED

7-0	Acute Oral LD ₅₀ (rat - for each active ingredient) [162.81(b)(3)(1)]	7-10	Acute Inhalation IC ₅₀ (rat - for each active ingredient) [162.81(b)(4)(1)(A)]	7-10	Dermal Sensitization (guinea pig - formulated product) [162.81(b)(4)(1)(A)]
7-2	Acute Oral LD ₅₀ (rat - formulated product) [162.81(b)(3)(1)]	7-11	Acute Inhalation IC ₅₀ (rat - formulated product) [162.81(b)(4)(1)(A)]	7-20	Dermal Photosensitization (guinea pig - for each active ingredient) [162.81(b)(4)(1)(A)]
7-3	Acute Oral LD ₅₀ (rabbit - for each domestic use dilution) [162.81(b)(3)(1)]	7-12	Acute Intraperitoneal (rat - for each active ingredient) [162.81(b)(4)(1)(B)]	7-21	Dermal Photosensitization (guinea pig - formulated product) [162.81(b)(4)(1)(A)]
7-4	Acute Dermal LD ₅₀ (rabbit - for each active ingredient) [162.81(b)(3)(1)]	7-13	Acute Intraperitoneal (rat - formulated product) [162.81(b)(4)(1)(B)]	7-22	Subacute Inhalation (rat - formulated product) [162.81(b)(4)(1)(B)]
7-5	Acute Dermal LD ₅₀ (rabbit - formulated product) [162.81(b)(3)(1)]	7-14	Acute Intravenous (rat - for each active ingredient) [162.81(b)(4)(1)(B)]	7-23	Subacute Oral (non-rodent mammal other than rabbit - for each active ingredient) [162.81(b)(4)(1)(C)]
7-6	Acute Primary Dermal Irritation (rabbit - for each active ingredient) [162.81(b)(3)(1)]	7-15	Acute Intravenous (rat - formulated product) [162.81(b)(4)(1)(B)]	7-24	Subacute Oral (mammal other than rabbit - for each active ingredient) [162.81(b)(4)(1)(C)]
7-7	Acute Primary Dermal Irritation (rabbit - for each active ingredient) [162.81(b)(3)(1)]	7-16	Subacute Dermal (rabbit - for each active ingredient) [162.81(b)(4)(1)(A)]	7-25	Teratology (mammal with hemochorial placenta - for each active ingredient) [162.81(b)(4)(1)(D)]
7-8	Acute Primary Eye Irritation (rabbit - for each active ingredient) [162.81(b)(3)(1)]	7-17	Subacute Dermal (rabbit - formulated product) [162.81(b)(4)(1)(A)]	7-26	Neurotoxicity (adult non - for each active ingredient) [162.81(b)(4)(1)(E)]
7-9	Acute Primary Eye Irritation (rabbit - formulated product) [162.81(b)(3)(1)]	7-18	Dermal Sensitization (guinea pig - for each active ingredient) [162.81(b)(4)(1)(A)]	7-27	Neurotoxicity (rat or dog - for each active ingredient) [162.81(b)(4)(1)(F)]

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7-25	Metabolism (rat or dog - for each active ingredient) [162.81(b)(4)(ii)(F)]	Z W NA O S	7-26	Mutagenicity - in vivo cytogenetic test (rat or mouse - for each active ingredient) [162.81(b)(4)(iv)(A)]	H R W NA O S	Any human data (such as patch test);
7-29	Metabolism (other species depending on use pattern - for each active ingredient) [162.81(b)(4)(ii)(F)]	E R W NA O S	7-37	Mutagenicity - specific locus test (mouse - for each active ingredient) [162.81(b)(4)(iv)(A)]	R W NA O S	
7-30	Carcinogenicity (rat - for each active ingredient) [162.81(b)(4)(iii)(A)]	S R W NA O S	7-38	Potentiation (for each active ingredient) [162.81(b)(4)(iv)(B)]	R U NA O S	
7-31	Carcinogenicity (most-sensitive mammalian species other than rat - for each active ingredient) [162.81(b)(4)(iii)(A)]	R W A O S	7-39	Re-entry (formulated product) [162.81(b)(4)(iv)(C)]	R W NA O S	
7-32	Chronic feeding (rat - for each active ingredient) [162.81(b)(4)(iii)(B)]	E R W NA O	7-40	Diagnostic Information [162.81(b)(4)(i)(c)]	S R W NA O	
7-33	Chronic Feeding (other species as determined by Reg.Div. - for each active ingredient) [162.81(b)(4)(iii)(B)]	R W NA O	7-41	First-aid information [162.81(b)(4)(i)(c)]	S R W NA O	
7-34	Reproduction (same rodent as chronic feeding study - for each active ingredient) [162.81(b)(4)(iii)(C)]	R W NA O	7-42	Palliative Information [162.81(b)(4)(i)(c)]	S R W NA O	
7-35	Mutagenicity - heritable translocation test (mouse - for each active ingredient) [162.81(b)(4)(iv)(A)]	S R W NA O	7-43	Antidotal Information [162.81(b)(4)(i)(c)]	S R W NA O	

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Now Currently Required

FISH AND WILDLIFE DATA REQUIREMENTS CHECKLIST		REGISTRATION NO. DATA SUBMITTED			
9-01	Avian Acute Oral LD ₅₀ (Mallard or Bobwhite each active ingredient) 162.82(a) 162.82(c)(1)(1)	9-10	Acute Toxicity, 96-hour LC ₅₀ (shrimp-for each active ingredient) 162.82(c) 162.82(2)(1)(1)	9-19	Invertebrate Reproductive Study (for each active ingredient) 162.82(c) 162.82(2)(1)(1)(1)
9-02	Avian Subacute Dietary LC ₅₀ (Mallard-for each active ingredient) 162.82(a) 162.82(c)(1)(1)	9-11	Acute Toxicity, 96-hour LC ₅₀ (shrimp-formulated product) 162.82(c) 162.82(2)(1)(1)	9-20	Invertebrate Reproduction Study (formulated product) 162.82(c) 162.82(2)
9-03	Avian Subacute Dietary LC ₅₀ (Bobwhite quail-for each active ingredient) 162.82(a) (c)(1)(1)	9-12	Acute Toxicity, 96-hour LC ₅₀ (crabs-for each active ingredient) 162.82(c) 162.82(2)(1)(1)	9-21	Field Study (formulated product) 162.82(c) 162.82(2)(1)(1)(A)
9-04	Fish Acute Toxicity, 96-hour LC ₅₀ (rainbow trout-for each active ingredient) 162.82(a) 162.82(c)(1)(1)	9-13	Acute Toxicity, 96-hour LC ₅₀ (crabs-formulated product) 162.82(c) 162.82(2)(1)(1)	9-22	Simulated Field Study (formulated product) 162.82(c) 162.82(2)(1)(1)(A)
9-05	Fish Acute Toxicity 96-hour LC ₅₀ (rainbow trout- formulated product) 162.82(c) 162.82(1)(1)	9-14	96-hour Acute Oyster Larvae LC ₅₀ --or-- American Oyster Shell Deposition (for each active ingredient) 162.82(c)(2)(1)(C)		
9-06	Fish Acute Toxicity 96-hour LC ₅₀ (bluegill-for each active ingredient) 162.82(a) 162.82(c)(1)(1)	9-15	96-hour Acute Oyster Larvae LC ₅₀ --or-- American Oyster Shell Deposition (formulated product) 162.82(c)(2)(1)(C)		
9-07	Fish Acute Toxicity 96-hour LC ₅₀ (bluegill-formulated product) 162.82(c)(1)(1)	9-16	Reproduction (Avian) (Bobwhite-for each active ingredient) 162.82(c) 162.82(2)(1)(1)(A)		
9-08	Invertebrate Acute Toxicity, 96-hour LC ₅₀ (Daphnia-for each active ingredient) 162.82(a) 162.82(c)(1)(1)	9-17	Reproduction (Avian) (Mallard-for each active ingredient) 162.82(c) 162.82(2)(1)(1)(A)		
9-09	Invertebrate Acute Toxicity, 96-hour LC ₅₀ (Daphnia-formulated product) 162.82(a) 162.82(c)(1)(1)	9-18	Chronic or Partial Chronic Fish Study (rainbow minnow for each active ingredient) 162.82(c)(2)(1)(1)(A)		

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To: Timothy A. Gardner
Product Manager (15)
Pesticides Registration Division (WH-567)

October 29, 1975

Environmental Protection Agency

From: Robert Heller
Division of Drug Labeling Compliance (HFD-312)
Bureau of Drugs
"CHIGG-AWAY" Distributed by Pierson Laboratories, Inc.
Lenexa, Kansas 66215

The proposed label and formulations submitted for "CHIGG-AWAY" indicate it is a preparation containing precipitated sulfur and benzocaine for the relief of itching and discomfort of bites from various non-poisonous insects. The preparation is, therefore, a drug for human use subject to the requirements of the Food, Drug, and Cosmetic Act (FDCA Act). In addition the label claims the product will repel chiggers causing it to be subject also to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) administered by EPA.

The proposed label and formulation was submitted to the FDA, Bureau of Drugs through our Kansas City field office and is submitted herewith along with FDA comments to EPA as per agreement.

The Over-the-counter Drug Review (OTC Drug Review) of the FDA currently in progress is expected to review such preparations as this in its review of miscellaneous topical OTC drug preparations. A call for data has already been published in the Federal Register, and a panel has convened to review such products for safety and efficacy.

Until the panel has concluded their recommendations and a finalized monograph covering such OTC products as this has been published in the Federal Register, we request certain interim label changes in the interest of safety in order for the product to be deferred to the OTC Drug Review. In addition, should EPA approve registration based on the claims applicable to FIFRA, Pierson Laboratories, Inc. must be informed that the marketing of "CHIGG-AWAY" at this time must be solely under their own responsibility with the realization that the results of the OTC Drug Review may affect the continued marketing of the drug.

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The interim label changes are as follows and should be included on all labeling as well:

1. The phrase "Do Not Take Internally" should be inserted after a hyphen following "For External Use Only".
2. The sentence beginning with "Discontinue use..." in the back panel "Caution" should be removed and replaced with the following "Not for prolonged use. If the condition for which this preparation is used persists or if a rash or irritation develops, discontinue use and consult physician".
3. The panel reviewing OTC topical analgesic preparations has expressed their concern over the use of benzocaine in infants due to the risk of possible methemoglobinemia. Although their conclusions are tentative and not final, we believe the warning suggested by the panel against use of benzocaine in infants should be included on any new benzocaine containing product proposing to enter the market. Therefore, the following statement should be placed separately and directly below the "Caution" statement on the back panel: "Warning: Not to be used in infants younger than two years because of risk of methemoglobinemia".

"Caution:"

We are infamiliar with the use of benzocaine at this extremely low level of 0.05% for topical anesthetic purposes, and we question the efficacy of its use at that level for that purpose.

For your information Pearson Laboratories, Inc. will only be the distributor of "CHICK-ANAY". They are responsible for the formulation and labeling; however, which they intend to provide to the manufacturer and packager: Adept Manufacturing, Inc. 570 S. Main, Brookfield, Missouri 64628.

We are enclosing along with out comments, the firm's petition for registration with EPA that was submitted to FDA for your disposition.

cc: KAN_DO (Attn: DeAnna Undersood)
HFD-510 (Geismar and Dec 1975) Heller
BRLC
OCP
HFA-226
HFD-300 r/f

Init:JMorrison:10/29/75
RHeller:lh:10/29/75

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MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

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HFD-312-16
HFD-312-16

TO : Bureau of Drugs/Division of Drug Labeling DATE: September 18, 1975
Compliance/OTC Compliance Branch/HFD-312

Re: Pierson Laboratories, Inc.
9515 Monrovia
Lenexa, Kansas 66215

FROM : Kansas City District
Compliance Branch (HFR-7140)

SUBJECT: Chigg-Away
OTC Drug

REVIEW AND COMMENT REQUESTED

The referenced firm has been in consultation with both EPA and this office regarding the marketing of the subject remedy. Since it contains claims for the relief of insect bites, it becomes FDA's primary jurisdiction. We are enclosing all submitted material, including the drug listing and registration form of the firm who is going to manufacture the product for Pierson Laboratories, and the forms EPA requested they complete. Following your review and if there is no adverse comments, please forward to EPA for their processing per memo of understanding between FDA and EPA. We would appreciate any comments you may have being directed to Mr. James D. Bender, Vice President, Pierson Laboratories, Inc., with copy to HFR-7140.

The firm intends to market the product in a 4 oz. and 8 oz. size. They have been advised of FPLA requirements insofar as type size of the net contents is concerned.

DeAnna Underwood

(Mrs.) DeAnna Underwood
Compliance Technician

DU/sd

Attachments

cc: EIR
RF
IBRF

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88.843

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HFD

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10/30/75

De Underwood -

as discussed in our
 letter of 10/29/75 re
 Precision Labs., Inc., I
 am returning the drug
 listing and registration
 forms covering Adapt
 Manufacturing, Inc. for
 Precision Labs. They should
 be sent back for submission
 by the firms to the proper
 location.

In addition you may
 extract my labeling
 comments from my memo
 to EPA in order to

offer labeling comments
 on "Chipp-away" to
 Precision Labs. If you
 have any questions please
 call (301-443-3750)

Robert Heller
 HFD-312

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191
Mr. H. S. Harrison
Registration Division (WH-567)
Environmental Protection Agency
Waterside Mall, East Tower
401 M Street, S.W.
Washington, D.C. 20460

Dear Mr. Harrison:

Enclosed please find EPA forms and supporting literature references for EPA application for registration of Chigg-Away. We have asked the EPA to forward this material to you along with the comments on the label as per our telephone conversation of September 8, 1975. During our conversation, you indicated that it would be possible to waive the 60 day waiting period and to assign an EPA number to our product without delay.

The EPA Form 8570-4, prepared by [REDACTED] and originally submitted June 9, 1975 with our EPA application for registration of Chigg-Away, was subsequently lost by the Registration Division. A copy of the cover letter regarding this form is enclosed.

Please note that the company name on our original application was S. L. Chigg Labs, 1012 Baltimore, Kansas City, Missouri. This has been changed and is now:

Pierson Laboratories, Inc.
9515 Monrovia
Lenexa, Kansas 66215

We would appreciate the expeditious handling of this application in every way possible.

Respectfully,

Thomas Behan

TB/mb

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Inert ingredient information may be entitled to confidential treatment

CHIGG-AWAY

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FRONT PANEL

NEW

Fights Chiggers 2 Ways!

CHIGG - AWAY

1. REPELS Chiggers! *pesticide claim*
2. RELIEVES itching of Chigger bites. *drug claim*

Caution: Keep out of reach of children. See back panel for further precautions and directions.

4 Fluid Ounces

BACK PANEL

CHIGG-AWAY
For External Use Only

Works Two Ways -

1. Effectively repels chiggers! Apply around ankles, waist and to skin under all areas of tight fitting clothing and around all openings in outer clothing. Re-apply after heavy exercise or swimming.
2. Relieves itching and discomfort of bites from chiggers, mosquitoes, ticks and biting flies. The unique action of Chigg-Away Lotion carries prompt relief to the source of irritation. Provides soothing relief from itching. Apply topically and rub in well as needed.

Caution: Keep away from eyes or other mucous membranes. Discontinue use if redness or rash develops. Do not use if allergic to benzocaine.

Active Ingredients:

Precipitated Sulfur 5%
Benzocaine 0.5%

Manufactured FOR
c 1975 Picson Laboratories Inc.
9515 Monrovia
Lenexa, Kansas 66215

EPA Reg. No.
EPA Est. No.

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92-91-37

84-843

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U.S. ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAM (W71-567) WASHINGTON, D.C. 20460 APPLICATION FOR NEW PESTICIDE PRODUCT REGISTRATION (Please read instructions on reverse before completing)		1. REFERENCE CODE		2. EPA USE ONLY	
		3. COMPANY/PRODUCT NO.		4. PROPOSED CLASSIFICATION <input checked="" type="checkbox"/> GENERAL <input type="checkbox"/> RESTRICTED	
5. NAME AND ADDRESS OF APPLICANT (Include ZIP Code) <div style="border: 1px solid black; padding: 5px; margin: 10px auto; width: 80%;"> PIERSON LABORATORIES, INC. 9515 Monrovia Lenexa, Kansas 66215 </div> <input type="checkbox"/> CHECK IF THIS IS A NEW ADDRESS				6. TYPE OF CONTAINER <input type="checkbox"/> METAL <input checked="" type="checkbox"/> PLASTIC <input type="checkbox"/> GLASS <input type="checkbox"/> PAPER <input type="checkbox"/> OTHER (Specify)	
				7. WILL CHILD RESISTANT PACKAGING BE USED? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	
8. PRODUCT NAME CHIGG-AWAY				9. EXPERIMENTAL PERMIT NO. N/A	
10. LOCATION OF LABEL DIRECTIONS <input checked="" type="checkbox"/> ON LABEL <input type="checkbox"/> ON MATERIAL ACCOMPANYING PRODUCT		11. MANNER IN WHICH LABEL IS AFFIXED TO PRODUCT <input checked="" type="checkbox"/> LITHOGRAPH <input type="checkbox"/> OTHER (Specify) <input type="checkbox"/> PAPER GLUED <input type="checkbox"/> STENCILED			
12. TYPES OF DATA SUBMITTED				FOR EPA USE ONLY	
01. NONE				1201	
02. PRODUCT CHEMISTRY				1202	
03. RESIDUE CHEMISTRY				1203	
04. ENVIRONMENTAL CHEMISTRY				1204	
<input checked="" type="checkbox"/> 05. EFFICACY				1205	
06. PHYTOTOXICITY				1206	
<input checked="" type="checkbox"/> 07. HUMAN SAFETY				1207	
08. DOMESTIC ANIMAL SAFETY				1208	
09. FISH AND WILDLIFE SAFETY				1209	
10. BENEFICIAL INSECT SAFETY				1210	
11. ACCIDENT EXPOSURE EXPERIENCE				1211	
12. OTHER (Specify)				1212	
13. OTHER (Specify)				1213	
13. METHOD OF SUPPORT (See instructions) <input type="checkbox"/> Required Supporting Data Attached. (2A) <input checked="" type="checkbox"/> Required Supporting Data is Submitted by Reference. (2B) <input type="checkbox"/> Proceed on the Basis of Established Use Patterns. (2C)		14. CONTACT POINT Complete items directly below for identification of individual to be contacted, if necessary, to process this application.		15. DATE APPLICATION RECEIVED (Stamped)	
OFFER TO PAY STATEMENT I hereby offer to pay reasonable compensation to the extent provided under Section 3 (c)(1)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, and in accordance with the Regulations and Guidelines published thereunder for use of any test data which has been submitted to the U.S. Environmental Protection Agency in connection with an application for the registration of a pesticide for the first time on or after October 21, 1972 and which may be used in support of the registration application for the subject pesticide.		NAME JAMES D. BENDURE		<div style="font-size: 2em; font-weight: bold;">BEST DOCUMENT AVAILABLE</div>	
		TITLE Vice-President			
		TELEPHONE NO. (Include Area Code) 913/642-7871			
16. SIGNATURE 		17. TITLE Vice-President		<div style="font-size: 2em;">43</div>	
18. TYPED NAME James D. Bendure		19. DATE SIGNED AUG. 27, 1975			

U.S. ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDE PROGRAMS (WH-567) WASHINGTON, D.C. 20460		1. COMPANY/REGISTRATION NO.	2. EPA USE ONLY
LABEL TECHNICAL DATA (See INSTRUCTIONS on back of last part)		3. PRODUCT NAME CHIGG-AWAY	
4. APPLICATION SITES (Check all that apply)	5. PEST TYPE (Check all that apply)	7. USER TYPE (Check all that apply)	
01 CROPS (Fruit)	01 ALGAE	01 UNSPECIFIED GENERAL USE	
02 CROPS (Vegetable)	02 AMPHIBIAN/REPTILE	02 UNSPECIFIED RESTRICTED USE	
03 CROPS (Field)	03 BACTERIA	X 03 HOMEOWNER USE	
04 CROPS (Spice)	04 BIRDS	04 JANITORIAL USE	
05 CROPS (Nut)	05 FISH	05 PEST CONTROL OPERATOR USE	
09 CROPS (Other)	06 FOULING ORGANISMS	06 COMMERCIAL APPLICATOR USE	
10 SOIL TREATMENT (No crop specified)	07 FUNGI	07 FARMER USE	
20 FOREST	X 08 INSECTS AND MITES	08 MEDICAL USE	
30 ORNAMENTALS	09 MAMMALS	09 VETERINARY USE	
40 TURF	10 NEMATODES	10 GOVERNMENT AGENCY USE	
50 STORED PRODUCTS TREATMENT	11 PLANTS	11 MANUFACTURING USE	
61 ANIMALS (Livestock)	12 RODENTS	8. FORMULATION (Check one only)	
62 ANIMALS (Dairy)	13 SLIME	01 TECHNICAL CHEMICAL	
63 ANIMALS (Pet)	14 SLUGS AND SNAILS	02 FORMULATION INTERMEDIATE	
64 ANIMALS (Laboratory)	15 VIRUS	03 DUST	
69 ANIMALS (Other)	16 OTHER (Specify)	04 GRANULAR	
71 OUTDOOR (Nocrop Agricultural)		05 PELLETTED/TABLETTED	
72 OUTDOOR (Resident/Commercial)		06 WETTABLE POWDER	
73 OUTDOOR (Non agricultural)		07 WETTABLE POWDER/DUST	
81 BUILDINGS (Agricultural)	6. MODE OF ACTION (Check all that apply)	08 CRYSTALLINE	
82 BUILDINGS (Commercial)	01 ATTRACTANT	09 MICROENCAPSULATED	
83 BUILDINGS (Food Processing)	02 BIOLOGICAL CONTROL	10 IMPREGNATED MATERIALS	
84 BUILDINGS (Medical)	03 CHEMOSTERILANT	11 SELF-GENERATING SMOKE	
85 BUILDINGS (Residential)	04 DEFOLIANT	12 EMULSIFIABLE CONCENTRATE	
91 EQUIPMENT (Commercial)	05 DESICCANT	13 INVERT EMULSION	
92 EQUIPMENT (Food)	06 FEEDING DEPRESSANT	14 FLOWABLE CONCENTRATE	
93 EQUIPMENT (Agricultural)	07 GROWTH INHIBITOR	15 SOLUBLE CONCENTRATE	
94 EQUIPMENT (Medical)	08 GROWTH REGULATOR	X 16 SOLUTION (Ready to Use)	
95 EQUIPMENT (Transportation)	09 POISON (Single dose)	17 OILS (No added pesticide)	
96 LAUNDRY AND DRY CLEANING	10 POISON (Multiple Dose)	18 PRESSURIZED (Gas)	
97 INDUSTRIAL PRESERVATIVES	11 PRESERVATIVE	19 PRESSURIZED (Liquid)	
98 PESTICIDE (Manufacturing only)	12 REPELLENT	20 PRESSURIZED (Dust)	
99 OTHER (Specify)	X 13 OTHER (Specify)	21 OTHER (Specify)	
Humans			

REMARKS:

See attached label copy.

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REPORT OF TELEPHONE CALL OR VISITOR			NOTE: Complete this form. Write "NA" where not applicable.
INCOMING CALL		VISITOR	DATE
OUTGOING CALL		CONGRESSIONAL	TIME OF CALL
NAME AND ADDRESS OF CALLER OR VISITOR <i>Ronald Ney } 222 Branch James Tonkey }</i>			PHONE NO. (Include Area Code or IDS No.)
			REGISTRATION, ID NO. OR FILE SYMBOL
			DATE OF LATEST SUBMISSION

BRIEF SUMMARY OF CONVERSATION

Is environmental chem. data required for this ~~the~~ product?

ACTION TAKEN OR RECOMMENDED

*Ney - No, better ask Tonkey - he has final say.
Tonkey - No, use does not warrant such data as stated
in Regs.; not to be used in "environment."*

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RECORDED BY (Name)

REFERRED TO (Name)

J. Ellenberg

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201

Product Name - Chigaway
Co. Name Pierson Labs

Active Ingredient - Sulfur

Name = Tom Behan

36864-1

(913) 888-9672

Has been cleared by FDA

Check with me

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TS

18/11/14

19/6

Check with Jay (75) 202

Mr Thomas Behan
36864-R

Tim

This Man is angry. Please
pull the file and write him

a letter telling him what is
necessary for registration / seal
as the date required.

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This is primary FDA & secondary
ours (EOA) This has been confirmed
write his new address on the back
of the yellow sheet.

Let me see the letter before

you send it. (See me Monday)

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W. H. Brown

333

704
PETERSON'S CHEMICAL CO.

1400 UNION AVENUE

KANSAS CITY, MO. 64101

Phone 816-342-3211

DATE 4-14 1975

We are attempting to register a product for the
S.T. Chigg Tabs as indicated on the enclosed 8370-4.
Will you release data on Microfins Sulfur in order
that we may proceed with registration.

SIGNED

H. R. W. Lane

REPLY

DATE

19

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NO. 9 FOLD

NO. 10 FOLD



SIGNED

334

Product ingredient source information may be entitled to confidential treatment

Mr. James M. Rea
TO Insect, Rodent Branch
Environmental Prot Agency
Wash. D.C. 20460

FROM

203
PATTERSON'S CHEMICAL CO.

1400 UNION AVENUE

KANSAS CITY, MO. 64101

Phone 816 - 842-8211

SUBJECT

CHIGG-AWAY (New Prod. Reg.)

MESSAGE

DATE

April 14 1975

Dear Mr. Rea:

Enclosed you will find all info necessary
for Registration of Chigg-away. We have requested
[redacted] to submit data on Sulfur as you
will note on enclosure. Will appreciate your
prompt handling. Thank you.

SIGNED

H. R. Mc Lane

REPLY

DATE

19

Please Address all correspondence on this
Registration to the Patterson Chemical Co.
1400 Union Ave.
Kansas City Mo 64101



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335

SUBMISSION REVIEW RECORD			1. REGISTRATION NUMBER				CYCLE	2. DATE RECEIVED		
3. 3CID PUBLICATION NECESSARY			4. PETITION NO.				5. RECEIVED PM TEAM			
6. METHOD OF SUPPORT			7. PRODUCT MANAGER				NO.	8. PROJECTED RETURN		
9. DATE PULLED		10. DATE PUBLISHED	11. ACTION TYPE				CODE	12. OUTGOING DATE		
REV. SEQ.	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER				COM-MENT CODE	DATE REVIEW COMPLETED		
								MO	DAY	YR
	A REVIEWABILITY TEAM									
	B PRODUCT MANAGER TEAM EFFICACY REVIEW									
	C PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW									
	D PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW									
✓	E PRODUCT MANAGER TEAM RESUBMISSION REVIEW	JSE				08J	1	2	7	5
	F PRODUCT MANAGER									
	G INTERAGENCY REFERRAL									
	H COST-BENEFIT REVIEW									
	I PUBLIC COMMENTS REVIEW									
	J EEE BRANCH INSECTICIDE EFFICACY									
	K EEE BRANCH HERBICIDE EFFICACY									
	L EEE BRANCH FUNGICIDE EFFICACY									
	M EEE BRANCH RODENTICIDE EFFICACY									
	N EEE BRANCH DISINFECTANT EFFICACY									
	O CHEMISTRY BRANCH RESIDUE CHEMISTRY									
	P EEE BRANCH ENVIRONMENTAL CHEMISTRY									
	Q TOXICOLOGY BRANCH HUMAN SAFETY									
	R EEE BRANCH ENVIRONMENTAL SAFETY									
	S									
	T									
PRODUCT MANAGER SIGNATURE			TYPE OF RESPONSE				CODE			
			BEST DOCUMENT AVAILABLE							

206

Registration Division

JUN 25

S. L. Chigg Laboratories
1012 Baltimore
Kansas City, MO 64101

Gentlemen:

Subject: CHIGG AWAY
EPA File Symbol 36864-R
Application of April 7, 1975

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is not acceptable for the reasons given below.

1. We are awaiting receipt of authorization to use the file of [REDACTED] ✓
Recd. 7-1-75
2. [REDACTED]. You must make allowance for the inerts from this product in your confidential formula.
3. Refer to the enclosed A-3 RET CHEMISTRY CHECKLIST, Comment Nos. 71 and 63.
4. Please submit data to support the label claim "repels chiggers." We lack background information to support this claim.
5. The front panel must bear the following additional precautionary labeling: The signal word "Caution."
6. The front panel precautionary labeling must meet the type size and prominence requirements. Refer to enclosed type size requirements sheet comment number 6.
7. Add the following fish and/or wildlife cautions in a separate paragraph: "Apply this product only as specified on this label."

Sincerely,

Gerald Harrison
Product Manager (17)
Insecticide Rodenticide Branch

Enclosures

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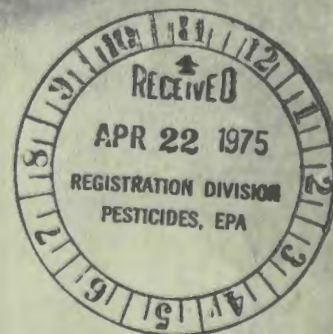
12
HFG

207

NO ACCEPTANCE
ACG. No. 36864-1



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338 13

REVIEW COMMENTS SHEET		1. Application Date 4/7/75	2. Registration No. 208 34844-R
3. Response Code A-5		4. Date Received 4/22/75	5. Telephone No. 4269425
6. Applicant Name & Address S. L. Chigg Laboratories 1012 Baltimore Kansas City, MO 64101		7. Originator	
8. Product Name Chigg AWAWY			

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COMMENTS

(1) We are awaiting receipt of ^{Authorization} authorization to use the file of [REDACTED]

You must make allowance for the inserts from this product in your confidential formula.

(3) T-71 and 63

4 Please submit data to support the label claim "really chigger". ^{we lock} ~~background~~ information to support this claim. ~~accepted use of self for chigger bite~~ ~~are made to but not as a repellent.~~

7 W-52, W-99

55-1(b) Caution

6 S-2, Refer to enclosed type size requirements sheet Comment number 6.

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SUBMISSION REVIEW RECORD			1. REGISTRATION NUMBER <i>1</i>		CYCLE	2. DATE RECEIVED <i>289</i>		
G			<i>36864 - N M N N R</i>			MO	DAY	YR
3. 3CID PUBLICATION NECESSARY			4. PETITION NO.			5. RECEIVED PM TEAM		
<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO						MO	DAY	YR
6. METHOD OF SUPPORT			7. PRODUCT MANAGER			8. PROJECTED RETURN		
<input type="checkbox"/> 2A <input type="checkbox"/> 2B <input checked="" type="checkbox"/> 2C			<i>Herald Harrison</i>			NO.	MO	DAY
						<i>17</i>		YR
9. DATE PULLED		10. DATE PUBLISHED	11. ACTION TYPE			12. OUTGOING DATE		
		<i>5-13-75</i>	<i>(51)</i>			CODE	MO	DAY
								YR
REV. SEQ.	REVIEW TYPE CODE	REVIEW TYPE	REVIEWER CODE (Initials)	SIGNATURE OF REVIEWER	COM-MENT CODE	DATE REVIEW COMPLETED		
						MO	DAY	YR
	A	REVIEWABILITY TEAM						
	B	PRODUCT MANAGER TEAM EFFICACY REVIEW						
	C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW						
	D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW						
	E	PRODUCT MANAGER TEAM RESUBMISSION REVIEW						
	F	PRODUCT MANAGER						
	G	INTERAGENCY REFERRAL						
	H	COST-BENEFIT REVIEW						
	I	PUBLIC COMMENTS REVIEW						
	J	EEE BRANCH INSECTICIDE EFFICACY						
	K	EEE BRANCH HERBICIDE EFFICACY						
	L	EEE BRANCH FUNGICIDE EFFICACY						
	M	EEE BRANCH RODENTICIDE EFFICACY						
	N	EEE BRANCH DISINFECTANT EFFICACY						
	O	CHEMISTRY BRANCH RESIDUE CHEMISTRY						
	P	EEE BRANCH ENVIRONMENTAL CHEMISTRY						
	Q	TOXICOLOGY BRANCH HUMAN SAFETY						
	R	EEE BRANCH ENVIRONMENTAL SAFETY						
	S							
	T							

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PRODUCT MANAGER SIGNATURE	TYPE OF RESPONSE	CODE
	<i>No Reply Necessary</i>	

Retype 5-23-20

SUBMISSION REVIEW RECORD			1. SUBMITTER'S NUMBER		2. YEAR		3. DATE RECEIVED		
G. 36864			0000		R		042275		
4. PETITION NO.			5. RECEIVED BY			6. PROJECTED REVIEW			
7. METHOD OF SUPPORT			7. PRODUCT MANAGER			8. PROJECTED REVIEW			
9. DATE PULLED			10. DATE PUBLISHED			11. ACTION TYPE			
APR 29 1975						12. OUTSIDE DATE			
13. REVIEW TYPE			14. REVIEWER CODE			15. SIGNATURE OF REVIEWER			
16. REVIEW CODE			17. COMMENT CODE			18. DATE REVIEW COMPLETED			
A	REVIEWABILITY TEAM	21C1K	E Kearny	OBJ	042875				
B	PRODUCT MANAGER TEAM EFFICACY REVIEW								
C	PRODUCT MANAGER TEAM HUMAN SAFETY REVIEW	WJTP	W. J. Power	OBJ	051675				
D	PRODUCT MANAGER TEAM ENVIRONMENTAL SAFETY REVIEW	"	"	"	"				
E	PRODUCT MANAGER TEAM SUBMISSION REVIEW	"	"	"	"				
F	PRODUCT MANAGER								
G	INTERAGENCY REFERRAL								
H	COST-BENEFIT REVIEW								
I	PUBLIC COMMENTS REVIEW								
J	EEC BRANCH INSECTICIDE EFFICACY								
K	EEC BRANCH HERBICIDE EFFICACY								
L	EEC BRANCH FUNGICIDE EFFICACY								
M	EEC BRANCH RODENTICIDE EFFICACY								
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O	CHEMISTRY BRANCH RESIDUE CHEMISTRY								
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Q	TOXICOLOGY BRANCH HUMAN SAFETY								
R	EEC BRANCH ENVIRONMENTAL SAFETY								
S									
T									
PRODUCT MANAGER SIGNATURE				TYPE OF RESPONSE				CODE	
				A-5				4	

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